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Lon L. Fuller

LAW AND CONTEMPORARY PROBLEMS

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FOREWORD

The lawyer is a respecter of precedent, at least to this extent: he is under obligation to accompany his departures therefrom with explanation, if not with apology. The American university law schools, in their contribution to the literature of the legal profession, have adhered with lawyerly consistency to an old and honorable precedent, established in 1887 by the first volume of the *Harvard Law Review*, a precedent from which its succeeding volumes and those of the many law school periodicals following it have not greatly deviated, however much they may have amplified and enriched it. *Law and Contemporary Problems* constitutes a marked departure from this precedent. Explanation is called for. This may, perhaps, best be achieved by a declaration of purposes.

Our social order has entered a period of accelerating change. Law is at once a barrier to such change and a mechanism through which it may be effected. Its relation to the problems of today cannot be ignored by lawyer or layman. Moreover, the thoughtful reader has grown wary of the ready pigeon-holing which classifies this problem as "legal," that as "economic," with the implicit assumption that never the twain shall meet. Yet though a "legal" problem may also be an economic, a political, or even a technological one, there persists the obstinate fact that the economist, the political scientist and official, the business man, and the technologist will make contributions to its comprehension or solution which, in all probability, will differ from that of one schooled in the legal discipline. Differences will obtrude, however earnestly the specialist has sought to assimilate the views and data outside the field of his particular competence. Syntheses differ with the synthesist. It is with this fact in view that *Law and Contemporary Problems* is organized in symposium form and that contributions to it have been solicited not only from lawyers but also from those who, whatever their profession, possess the knowledge and experience which vouches for the significance of their commentary on the subject under discussion. The reader, whether lawyer or layman, may profit from contrasts and conflicts as well as from reconciliations.

The subjects selected for consideration will, of course, be those in which the legal factor is prominent, integral either to the problem itself or to its solution. Low-cost housing, agricultural marketing, interstate crime control, our migratory divorce jurisdiction, limitations on testamentary power on behalf of the testator's immediate family, arbitration as a substitute for litigation, the security devices of the installment

seller—these are typical of the topics on which *Law and Contemporary Problems* will be focussed. In the treatment of such topics, no fetish will be made "objectivity." The expression of opinion and belief, however controversial, will be sought because opinion and belief have themselves a social significance when expressed by competent and thoughtful observers which is independent of their ultimate verification or contradiction by experience. Moreover, in the selection of contributions, there will be no pretense of maintaining a nice balance between the views of the proponents and the opponents of change, between the advocates of this solution or that. To do so would constitute an achievement of doubtful value which limitations of space would seldom make possible.

A word as to the present issue. Plans had been laid for it prior to the entry on the scene of a new factor of major importance, the Food and Drugs Bill, now pending in Congress. The bill represents the first far-reaching effort since 1906 to augment the legal safeguards of the consumer. Whatever its fate in the coming session, its provisions must hereafter be examined by students of legislation in this field. In making room for its consideration, other aspects of the problem had to be discarded, among them, state and local regulatory activities and the valuable work of certain non-governmental bodies such as the Better Business Bureaus. An eleventh-hour disappointment prevented the intended presentation of the drug manufacturers' criticism of the pending bill.

The department of student work usual in "law reviews" will not be included in *Law and Contemporary Problems,* although students of high standing in the Duke University School of Law will be invited to contribute articles on legal subjects. The customary student comment on current decisions will appear as a department of the *Duke Bar Association Journal,* a periodical published three times a year by the Duke Bar Association, a student organization.

THE STRUGGLE FOR FEDERAL FOOD AND DRUGS LEGISLATION

C. C. Regier*

In a simple agricultural society the problem of food supply devolves upon every family. Nearly every family produces its own supply, and those who do not produce it themselves obtain it from their neighbors or in the local market. The effects of neglect or carelessness in the matter of sanitation fall upon the producers themselves.

This is different in an industrial society. There a large proportion of the population is entirely dependent upon the general market. People buy their food at the stores, often chain-stores, which have imported it from distant places, much of it in cans or packages. Usually only a small part of the food which is consumed in any community has been produced in that locality. Much of it has come from other states and countries. And what is true in this respect of food is also true of drugs, narcotics, and liquors.

Under the police power a state may protect its citizens in health, welfare, and morals; but how can a state protect the health of its citizens effectively when so much of what they consume comes from the outside? (Then, too, it must be remembered that the exercise of jurisdiction by a state over goods from without its borders is subject always to the risk that the Supreme Court will regard its action as an "unreasonable interference" with interstate commerce.)

The transition from an agricultural to an industrial society is a gradual process. In the United States it came about during the second half of the nineteenth century. The federal law-makers, however, were not willing to face this fact squarely—as far as the food situation was concerned—until the twentieth century was well on the way. To describe briefly the movements, forces, and events which brought about this change in legislation is the aim of this article.

The first step in the struggle to guarantee pure food and drugs by law was taken in 1850. In that year a federal statute was passed which provided for the classification of tea and for the exclusion of certain kinds.[1] Between January 20, 1879, and June 30, 1906, when the Food and Drugs Act was passed, 190 measures were presented in Congress which were designed in some way to protect the consumer of

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[1] Wiley, An Autobiography (1930) 198.

food and drugs. "Of these, eight became law, six passed the House but not the Senate, three passed the Senate but not the House, twenty-three were reported favorably from the committee to which they had been referred, nine were reported back adversely, and 141 were never heard of after their introduction."[2]

Professor Thomas A. Bailey, in an illuminative article on "Congressional Opposition to Pure Food Legislation, 1879-1906," claims that it was understood from the beginning that a sweeping pure-food law could not be obtained all at once; that the movement was a gradual evolution from specific laws on definite articles, such as those on glucose, cheese, meat, lard, butter, oleomargarine, baking powder, tea, drugs, canned fish, to the general law of 1906; and that "it was comparatively easy to pass a measure governing the importation of foreign goods, less easy to regulate exported goods, less easy to improve food conditions in the District of Columbia, and exceedingly difficult to prohibit adulterated foods in interstate commerce."[3]

At first there was very little interest in this sort of legislation. It was regarded as the work of cranks and reformers. In 1884 a resolution was introduced in the House authorizing an investigation of adulterated food and drugs by the Committee on Public Health, but it received only fourteen favorable votes. Two years later a tax was placed on oleomargarine, to which the South was almost solidly opposed, for cotton-seed oil went into the manufacture of this product. Between 1887 and 1892 hundreds of petitions were sent to Congress protesting against the manufacture of compound lard. This precipitated a contest between the cotton-seed oil producing states and the hog raising states. Congress would not act, and so the agitation collapsed. In 1890 a law was passed which provided for the inspection of meat for export and for the prohibition of importation of adulterated food and drinks. This was largely caused by the refusal on the part of Germany and France to receive diseased meat from this country. In the 51st Congress (1889-91) Senator Paddock of Nebraska sponsored the first general pure food bill. He tried, vainly, on four separate occasions to secure action on the bill. Always there were appropriation bills in the way. In the next Congress he succeeded in inducing the Senate to pass such a bill, only to have the House give it a lingering death.

There seemed to be an understanding between the two houses that when one passed a bill to repress food adulteration the other would see to it that it was buried.[4] In the later stages of the struggle, when it had become dangerous to oppose such measures openly, the proponents of pure food bills encountered great difficulty in getting the bills called up at all. Excuses were always found. Among the most common were: more pressing legislation, agreement in principle but opposition to construction, the desirability of letting the states handle their own problems in their own way, and the prevention of hasty legislation.[5]

The opposition to pure food legislation came chiefly from three classes. First,

[2] Bailey, *Congressional Opposition to Pure Food Legislation* (1930) 36 AM. J. SOC. 52.
[3] *Id.*
[4] WILEY, *op. cit. supra* note 1, at 202.
[5] Bailey, *supra* note 2, at 58.

there were those who objected on constitutional grounds. They did not wish to have the federal government extend its police power into the states. This opposition came largely from southern Democrats. Secondly, there were many who did not realize the seriousness of the problem. And finally, there were some who were personally interested in the perpetuation of frauds that would be illegal under a pure food statute.[6] The objection from the first two groups almost disappeared as the issue became clearer and public opinion more insistent, but the third class fought to the bitter end, although mostly under cover. Many of the congressmen feared to oppose the powerful business interests, for on big business most of the Republican senators and House members and practically all the more powerful ones, depended for re-election.[7]

In the 57th Congress (1901-1903) and the 58th (1903-1905) pure food and drugs bills were pressed with great vigor. In the House, Hepburn of Iowa was in charge, and Mann of Illinois very ably supported him. They were able to induce the House to pass the measure in each Congress; in the latter, by a vote of 201 to 68. In the Senate, where the special interests were more firmly intrenched, it was more difficult. Here McCumber of North Dakota and Heyburn of Idaho were the chief advocates. They experienced great difficulty in getting the measure called up. When on February 25, 1903, a vote was taken to take up the bill, it was voted down 32 to 28. Two years later it came to a debate, but no vote. Among those who raised objections were Aldrich of Rhode Island, Lodge of Massachusetts, Hale of Maine, Kean of New Jersey, Frye of Maine, Foraker of Ohio, Platt of Connecticut, Spooner of Wisconsin, Hanna of Ohio, Cullum of Illinois, and Gallinger of New Hampshire—all Republicans.

Before Congress could be induced to act, it was necessary for public opinion to assert itself more vigorously, and that finally came about in no uncertain terms. As in many other matters, the legislation in favor of pure food was the result of a long process of education and agitation.

The resentment began with the farmers.[8] They objected to the adulteration of milk, butter, lard, and other food products. They established state departments of agriculture, and provided themselves with state chemists whose duty was to analyse foods in order to detect imitations and adulterations. This led to an interest in the whole problem of sanitation and to food legislation. By 1906 practically all the states had pure food laws. In 1898 the National Association of State Dairy and Food Departments was organized, and this association held annual meetings. It was soon apparent that only a national law would be adequate. The states, acting separately, could not protect themselves against interstate commerce, and by establishing different standards, they made it very difficult for the manufacturer to meet them all. The more reputable manufacturers of food products were not slow to appreciate that a federal law would be to their interest, but, as long as their competitors were

[6] *Id.* at 64.
[7] 2 SULLIVAN, OUR TIMES (1929) 526. [8] *Id.* at 516.

allowed to imitate the goods of others and to adulterate and misbrand their own, they found themselves in a difficult position.

In the long crusade for pure food and drugs, the outstanding figure was Dr. Harvey W. Wiley. He was "a very mountain among men, a lion among fighters."[9] At the same time he was a "keen student of human nature" and a "prince of good fellows."[10] Not only was he an efficient scientist and investigator but also an effective writer and speaker. After a short but brilliant career as a chemist in Indiana, particularly at Purdue University, he was appointed Chief Chemist in the Department of Agriculture. This position he held from 1883 to 1912. When Congress created the Bureau of Chemistry in the Department of Agriculture, he was made the chief of the new bureau.

When he entered upon his government duties he found much work to be done. After years of unrelenting activity in behalf of unadulterated food, he published his *Bulletin No. 13,* Bureau of Chemistry. This covered practically all classes of human food, and did much to create interest in the subject. Other reports, books, and articles followed from his prolific pen. In 1902 he organized what came to be known as "Doctor Wiley's poison squad." This was an attempt to test the effect of commonly used food preservatives on the health of certain young men of the Department of Agriculture. These experiments were carried on for five years and proved conclusively that such preservatives are harmful to health.[11] The press carried the reports of these investigations all over the world.

That his official position was not free from anxiety and interference may be inferred from what he says about the man who was his superior for fifteen years, Secretary of Agriculture James Wilson (1897-1913). Mr. Wilson, he wrote in later years, "had the greatest capacity of any person I ever knew to take the wrong side of public questions, especially those relating to health through diet."[12] It was fortunate for Wiley, however, that he had good friends on the House Committee on Agriculture. These saw to it that the appropriations for the Bureau of Chemistry were not cut off.

About the time when Wiley organized his poison squad, the so-called muckrakers appeared upon the scene. They ruthlessly exposed a great variety of corruption and fraud, including all those interests which opposed the passage of a pure food and drugs act. Among these may be mentioned all those who were preserving foods by means of chemicals; the manufacturers of articles which were used in the adulteration of food and drugs; the "rectifiers," or producers of fraudulent whisky out of alcohol, colors, and flavors; the patent-medicine manufacturers; and the dishonest misbranders and mislabelers of food and drug products. Long before the era of the muckrakers had come to a close, the Food and Drugs Act of 1906 was safely on the statute books.

[9] *Id.* at 520.
[10] Bigelow, *Obituary—Harvey Washington Wiley* (1930) 72 SCIENCE, 311, 312.
[11] WILEY, *op. cit. supra* note 1, at 215-220. [12] *Id.* at 190.

The Ladies Home Journal and *Collier's Weekly* waged a determined campaign against the patent medicine fraud. Edward Bok and Mark Sullivan wrote for the former, and Samuel Hopkins Adams for the latter. Adams was easily the outstanding muckraker in this field.[13] In 1905 and 1906 he wrote twelve articles under the general title "The Great American Fraud." Of these seven appeared before the act of 1906 was passed. He compared the chemical analyses with the curative claims of scores of patent medicines. Many of these contained alcohol, opium, or cocaine as the chief element. "Liquozone," he claimed, was composed of nine-tenths of a per cent of sulphuric acid, three-tenths of a per cent of sulphurous acid, and nearly ninety-nine per cent of water. And this was advertized to cure thirty-seven varieties of diseases.[14] "Peruna" contained twenty-eight per cent of alcohol and often led to tuberculosis and drunkenness. It cost eight and a half cents to produce and sold for a dollar.[15]

Years later he described the conditions which prevailed before the passage of the act of 1906 in these words: "Floods of potions, avalanches of pills and powders, had been pouring out from the various nostrum shops, without let or hindrance, to overflow the land. Seventy-five million dollars a year is a moderate estimate of the volume of business done by pseudo-medical preparations which 'eradicated' asthma with sugar and water, 'soothed' babies with concealed and deadly opiates, 'relieved' headaches through the agency of dangerous, heart-impairing, coal-tar drugs, 'dispelled' catarrh by cocaine mixture, enticing to a habit worse than death's very self, and 'cured' tuberculosis, cancer, and Bright's disease with disguised and flavored whiskies and gins."[16]

The patent medicine interests were organized under the name "The Proprietary Association of America." It wielded a tremendous influence over the press through its advertisements. Wiley estimated that the newspapers and periodicals received $100,000,000 a year from advertising patent medicines.[17] *Collier's* exposed their methods of muzzling the press. In order to prevent adverse legislation, President F. J. Cheney of the Association inserted in his advertising contracts with some 15,000 newspapers this clause: "It is mutually agreed that this contract is void if any law is passed in your state prohibiting the manufacture or sale of proprietary medicines."[18] Others made the contracts even stronger. Few publishers would jeopardize their income from this source.

Scores of articles appeared in 1905 and 1906 which dealt with the patent medicine evil and the adulteration of food. Even Senator McCumber of North Dakota had an article in the *Independent* which was entitled "The Alarming Adulteration of Food and Drugs." In it he presented many facts which Professor E. F. Ladd, the Food Commissioner of his own state, had discovered. Ladd had never yet found a can

[13] Adams, as well as Wiley, was in close contact with congressional leaders during the final stages of the legislation for pure food and drugs.

[14] Adams, *Liquozone*, COLLIER'S, Nov. 18, 1905.

[15] COLLIER'S, Oct. 28, 1905.

[16] Adams, *The Fraud Medicines Own Up*, COLLIER'S, Jan. 20, 1912.

[17] WILEY, *op. cit. supra* note 1, at 208.

[18] COLLIER'S, Nov. 4, 1905.

of potted chicken or potted turkey in North Dakota which contained chicken or turkey in determinable quantities. Of the local markets of his state, ninety per cent used chemical preservatives. The amount of borax or boracic acid which was used in sausages and hamburger steak ranged from twenty to forty-five grains per pound though the daily medical dose was only from five to nine grains. Nearly every imported ham contained borax. Boracic acid or borates were common ingredients of dried beef, smoked meats, canned bacon, and canned chipped beef. Ninety per cent of the so-called French peas were found to contain copper salts, and some contained aluminum salts in addition. Only one kind of catsup was free from chemical preservatives and coal tar coloring matters. About seventy per cent of cocoas and chocolates were adulterated, and glucose served a great variety of purposes. More than ten times the amount of Vermont maple syrup was sold every year than that state could produce. A large proportion of ground spices were imitations. Jellies, wines, and other liquors were made from cheap substances and then doctored up. Butter was a mixture of butter and deodorized lard. Ice cream contained no cream, only condensed milk and neutral lard. Cider vinegar usually contained no apple juice. Drugs were adulterated and misbranded in a similar fashion, often with deplorable consequences.[19]

Walter Lippmann claimed that a vivid description of food conditions would reveal revolting conditions, "Milk would curdle the blood, bread and butter would raise a scandal, candy—the volume would have to be suppressed.[20] Jelly, stated another writer, was made out of apple cores, apple parings, and cheap apples. It was put into a large tank. As orders were received for various kinds of jellies, they were all filled from this same tank. Color and flavor were added as the demand required.[21] The same practice was followed by the liquor dealers, as was revealed in the congressional debates.[22]

The meat industry, too, was under attack. Beginning with February, 1905, Charles Edward Russell ran eight articles in *Everybody's* under the imposing title "The Greatest Trust In the World." He began the series with this statement: "In the free republic of the United States of America is a power greater than the government, greater than the courts or judges, greater than legislatures, superior to and independent of all authority of state and nation." No king or emperor or irresponsible oligarch, he went on to say, had ever wielded such power. It existed and proceeded in defiance of law. It, the Beef Trust, like the Standard Oil Trust, rested solely and squarely upon railroad rebates. These rebates had been received from all the railroads in spite of the Interstate Commerce Act. For 1905, Mr. Russell estimated, these rebates would probably amount to $25,000,000. Although the rebates were in this case called "private car charges," the effects were the same. Through

[19] McCumber, *The Alarming Adulteration of Food and Drugs*, INDEPENDENT, Jan. 5, 1905.
[20] LIPPMANN, DRIFT AND MASTERY (1914) 7.
[21] Lowry, *The Senate Plot Against Pure Food*, WORLD'S WORK, May, 1905.
[22] 40 CONG. REC. 1218 (1906).

perfection of organization this trust had managed to increase the retail prices of meat in spite of the fact that the value of beef cattle in the United States had declined by $163,000,000 in the three years ending January 1, 1905.

Collier's Weekly also participated in this controversy. It commented on the damaging charges against the Chicago slaughterhouses which the English periodical, *Lancet,* made early in the same year. The *Lancet* articles were also an indictment of the government meat inspection service. And the denial of the charges on the part of the packers afforded Upton Sinclair an opportunity to write some scathing articles on the subject.[23]

The most sensational piece of literature concerning this matter, however, was not so much the product of typical muckraking as of fictional propaganda. After having spent seven weeks in "Packingtown" where he talked with workingmen, bosses, superintendents, night-watchmen, saloon-keepers, politicians, clergymen, and settlement-workers, Upton Sinclair wrote his famous novel, *The Jungle.*[24] In it he told of the tragedies which befell a Lithuanian peasant while working in the Chicago meat-packing establishments. The book was meant to be propaganda for socialism, but what the public noted most were the bits of information which it gave about the unsanitary conditions which prevailed in the packing houses and the unclean meat that was sold to the public. Sinclair described how diseased cattle were butchered, marked by the government inspectors, thrown into dumps, loaded on carts and wheeled back again and mingled with other carcasses and treated and sold as clean meat. Animals that had died on the trains in transit were unloaded in the stockyards at night and treated as pure meat. Some of the descriptions of the filth and dirt that prevailed in the packing houses were utterly revolting. It is no wonder that many people lost temporarily their appetite for meat. The author said later he aimed at the public's heart and by accident hit it in the stomach. *The Jungle* was the best selling book for a year in the United States, Great Britain and her colonies. It was translated into seventeen languages, and by 1922 about 150,000 copies of it had been sold.[25]

The women, too, had a share in this campaign of education and agitation. The General Federation of Women's Clubs organized a Pure Food Committee in 1904. This committee wrote some two thousand letters, sent circulars to every state, and tried by letters, talks, exhibits, and literature to arouse interest in the subject. It memorialized the President, the Secretary of Agriculture, the Senate and the House of Representatives, and kept up a newspaper warfare.[26] It has been said that the women did more in this crusade without votes than they have done since 1919 with votes.[27]

[23] Sinclair, *Is Chicago Meat Clean?* COLLIER'S, April 22, 1905; *Stockyard Secrets,* COLLIER'S, March 24, 1906; *The Condemned-Meat Industry,* EVERYBODY'S, May, 1906.

[24] Sinclair, *What Life Meant to Me,* 41 COSMOPOLITAN, 591-595.

[25] So stated in a personal letter to the writer from Upton Sinclair, June 30, 1922.

[26] Report of the Pure Food Committee of the General Federation of Women's Clubs (1906) 28 ANN. AM. ACAD. OF POL. AND SOC. SCI. 296.

[27] SULLIVAN, *op. cit. supra* note 7, at 522.

After all this clamor—or rather, while the clamor was going on—Congress could no longer dispose of this matter by mere obstruction. In his message of December 5, 1905, President Roosevelt briefly but forcefully called for legislation on the subject of misbranding and adulterating foods, drinks and drugs. In the same month Senator Heyburn re-introduced his bill, Senate bill No. 88, "for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicine, and liquors, and for regulating traffic therein, and for other purposes."

On January 10, 1906, he got the bill up for consideration. In his speech he pointed out the new features of this bill. In the first place, it held the officers of a corporation personally responsible for offenses, and in the second place, it separated liquors from food. Heyburn then proceeded to discuss the difficulty in which the states found themselves. "There are a number of fraudulent articles that are under the ban of this legislation, not a pound or ounce of which is offered for sale in the state in which it is manufactured, because they are provided against by the legislation of that state; but they are manufactured in one state and sent to another in unbroken packages under the rule of law that is now established, perhaps forever. So that the state into which they are sent is helpless against a flood of these impure articles sent in unbroken packages under the protection of that rule of law and then offered for sale upon the retail market."[28] In some states, he went on to say, sixty per cent of the drugs were adulterated, and Congress must meet the states half way. Heyburn later (February 21) had a resolution and a report read from the American Medical Association which endorsed the Heyburn bill. It claimed to represent the conviction of 135,000 physicians in 2000 counties.[29]

McCumber said the public and the press demanded action. "A great number of the leading magazines" were devoting considerable attention to the contents of this bill, and all the honest manufacturers were for it. He, then, proceeded to explain from what sources the opposition came. The whiskey blenders, who were organized in the National Association of Liquor Dealers, had boasted that they alone had prevented the Senate from acting on this bill in the last two Congresses. Then there were the wine merchants and those merchants who sold cotton-seed oil for French olive oil. Besides these, there were some manufacturers of jellies. These were practically the only opponents of the bill, he said.[30] But he should have included the patent medicine fraternity. This he later did, and stated that it was perhaps true that ninety-five per cent of patent medicines were frauds and that ninety-five per cent of the drugs sold were patent medicines or proprietary medicines.[31] The annual value of adulterated food, he estimated at three billion dollars.[32]

Senator Aldrich, the Republican leader in the Senate and an old enemy of pure food legislation, found himself obliged to fight in the open this time, a thing he

[28] 40 CONG. REC. 894-5 (1906).
[29] *Id.* at 2748.
[30] *Id.* at 1216-1218.
[31] *Id.* at 2661-5.
[32] *Id.* at 1414.

rarely did. Early in the debate he made a one-minute speech in which he tried to make the measure seem ridiculous by raising the question as to whether the time had come when Congress should prescribe for the people of the United States what they should eat and drink. To this McCumber replied, in effect, that the contrary was the truth, that this bill was intended to make it possible for everybody to buy the kind of food he wanted to eat.

Senator Money of Mississippi offered a substitute for S. 88. His bill had been drafted by the secretary of the National Food Manufacturers' Association and had the approval of three hundred food manufacturers.[33] McCumber pointed out that the substitute bill would interfere with state pure-food laws, would be very difficult of enforcement, gave the manufacturers undue protection and advantages, and did not cover the patent medicines.[34]

The two Senators who bore the brunt of the fight for the bill were Heyburn, who was in charge, and McCumber. Among those who raised objections were Aldrich, Money, Bailey, Foraker, Spooner, Gallinger, Hemenway, Lodge, and Penrose. The vote in the Senate was taken on February 21, 1906, and passed by 63 to 4, not voting 22. The four voting against the bill were Bacon of Georgia, Bailey of Texas, Foster of Louisiana, and Tillman of South Carolina. All four objected to the bill on constitutional grounds. Bailey insisted that the bill was "purely and only an exercise of the police power, and therefore not within the power of the federal government."[35]

Four months elapsed before the House of Representatives gave the bill its serious attention. Then it gave parts of three days—June 21, 22, 23—to its discussion. Hepburn of Iowa was in charge of the bill, but Mann of Illinois opened the debate. He stated that the delay had been due to appropriation bills, and that the leaders of the House had constantly assured the proponents of pure food legislation that this measure would be taken up. He said that after S. 88 had been referred to the House Committee on Interstate and Foreign Commerce, this committee struck out everything after the enacting clause and substituted for it the House bill. He explained the differences between the two bills, which were not important, except that the House bill provided for the fixing of food standards and that it had a provision on narcotics, which S. 88 did not have. He showed that many people had been misinformed as to the difference between the two bills. They had been led to believe that it was the Senate bill which dealt with narcotics, and so they demanded that the Senate bill be passed.[36] He intimated that it was the Proprietary Association which had inspired this impression.

A long minority report was submitted by members of the committee, signed by Adamson and Bartlett of Georgia and Russell of Texas. The whole contention of the minority report was that the federal government had no right to extend its police

[33] *Id.* at 2652-8.
[34] *Id.* at 2661-5.
[35] *Id.* at 2760.
[36] *Id.* at 8889-8900, 9735-9740.

powers into the states.[37] This was also the import of the speech which Adamson, as leader of the opposition, made on this occasion. "The truth about it is," he claimed, "the bill from first to last, violates every principle of our government by proposing to go into sumptuary legislation for the regulation of the table menu, and I suppose the next step will be to prescribe the table etiquette and dress." Applause greeted him when he said, "I believe there are millions of old women, white and black, all over my country, who know more about victuals and good eating than my friend Doctor Wiley and all of his apothecary shop."[38]

After a lively, though not acrimonious, debate in which there were frequent allusions to Wiley, Adams, and the excitement of the public, the House passed its own bill with a vote of 241 against 17. In the ensuing conference committee Heyburn, McCumber, and Latimer represented the Senate, and Hepburn, Mann, and Ryan, the House. All the important features of the Senate bill were retained, and the provision on narcotics was added. The House clause for the creation of food standards was eliminated.[39] In this form both houses agreed to the conference report on June 29, 1906. The next day it received the President's signature.[40]

Before the House took up the consideration of the Hepburn bill, the Senate had started another important food measure.

For some time the meat industry had been under attack. In February, 1906 *The Jungle* was published. Senator Beveridge of Indiana read it in March and called it to the attention of Roosevelt, not knowing that the latter had seen it in manuscript.[41] Roosevelt was especially impressed with the reflections it cast on the government inspection service. He called Secretary Wilson's attention to it, who sent three men from the Department of Agriculture to Chicago to make an investigation. Conscious of the public excitement that had been aroused and fearing that the investigation by the agricultural department would result in a "whitewashing" report, Roosevelt sent a commission of his own to bring in a report. His investigators were James Bronson Reynolds, a reformer, and Charles P. Neill, a United States labor commissioner.

Unconscious of this investigation, Beveridge informed the President that he was

[37] *Id.* at 8910-8915. [38] *Id.* at 8955-6.

[39] The absence of such standards embarrassed the administration of the Act, and it is interesting to note that when, in 1930, the McNary-Mapes Bill was introduced to empower the Secretary of Agriculture to establish standards for canned products other than meat and milk, it passed both houses after brief discussion and without any serious opposition. Senator McNary said during the discussion that "the bill now receiving the attention of the Senate passed the House without any opposition. It is a bill proposed by the Department of Agriculture, has the approval of the canners throughout the country and of the Consumers' League, and I know of no opposition to it, aside from that of those who desire not to be exposed in their canning of inferior vegetables. The bill would simply permit the Secretary of Agriculture to formulate a grade for canned goods, so that if in the canning process such goods shall fall below that grade, they would have to be so branded." 75 CONG. REC. 10164 (1930).

[40] Dr. Wiley felt that Roosevelt had been given undue credit for his efforts in behalf of the Food and Drugs Act. WILEY, *op. cit. supra* note 1, at 231. Mann, while explaining the conference report to the House on June 29th, claimed that Representative Hepburn of Iowa was "principally entitled to the credit for the enactment of a pure-food law" (a statement which might be challenged).

[41] 40 CONG. REC. 9735-9740 (1906).

drafting a meat inspection bill. The latter advised him to wait until Reynolds and Neill came back. On their return he consulted with them and continued working on his bill, drafting it about twenty times and sending every third or fourth draft to Wilson for comment.[42] On May 25 he offered it as an amendment to the Agricultural Appropriation Bill, and it was adopted without debate or reference.

The amendment provided that the Secretary of Agriculture should cause post-mortem examinations to be made of slaughtered cattle, sheep, swine, and goats; food products should be inspected; slaughtering and canning establishments should be kept in a sanitary condition; animals should be inspected before slaughtering; canned meat should bear the date of inspection on the label; inspections should be made also during the night; a fee should be charged for this service; animals for export should be inspected; labels on canned goods must not be falsified; but the act should not apply to farmers who might engage in local commerce.

The packers became frantic and tried to hush things up quickly. They inspired more than a thousand telegrams to Roosevelt, protesting against the publication of the Neill-Reynolds report; they induced the live-stock raisers of the country to support them; and they tried to intimidate the President and his commissioners.[43] At the same time they began a feverish clean-up of the packing houses.[44]

When the bill came to the House, it was referred to the Committee on Agriculture. Here efforts were made to emasculate the meat inspection amendment. Chairman James W. Wadsworth of the committee was friendly to the packers, and in the hearings which he conducted he seemed to favor the meat industry. But Roosevelt was determined that the teeth should not be pulled out of the bill. He had received the Neill-Reynolds report on June 2, and two days later he sent an urgent message to the House, advocating the acceptance of the Beveridge amendment, and at the same time he sent the first part of the much-feared report, which was immediately broadcast by the press. This compelled favorable action on the part of the committee. When the bill was reported to the House on June 19 the teeth had all been restored except two. It did not provide for the date on the label, but it did provide that $3,000,000 be permanently appropriated for meat inspection, thus relieving the meat industry of that expense. In that form the bill was passed by a large vote, although not without severe criticism.

By this time the packers had changed their attitude. Thomas E. Wilson, one of the large Chicago packers, testified before the committee that the sale of meat and meat products had been more than cut in two, and another packer stated that every country in Europe had taken up the agitation and that it was hurting American business. They began to realize that government inspection was the only thing that could save their business, for that alone could restore the confidence of the public;

[42] BOWERS, BEVERIDGE AND THE PROGRESSIVE ERA (1932) 228.
[43] *Id.* at 229.
[44] SULLIVAN, *op. cit. supra* note 7, at 533-540.

so they faced about and supported inspection. But they did not want to bear the cost of inspection, nor did they want the date on the label.

When the House message came before the Senate on June 20, it provoked both disappointment and satisfaction. Beveridge claimed the House bill was a much better one than any informed man had any right to expect during that session.[45] Lodge used strong language on this occasion. He said "those packers in Chicago and those owners of the Standard Oil have done more to advance socialism and anarchism and unrest and agitation than all the socialistic agitators who stand today between the oceans." He wanted "that group of men" to be put on a level with other Americans.[46] McCumber felt sure that the packers would shift the inspection fee to somebody else, because it was absolutely within their power to determine what they should pay for the live-stock and what they should charge the consumer of the meat.[47] Warren of Wyoming, "the greatest shepherd since Abraham," was almost the only Senator who argued for the House measure. That, he said, had the support of the House of Representatives, of the Speaker, of the President, and of many Senators. Why should it not be a Roosevelt-Beveridge-Cannon-Wadsworth act?[48]

Most of the Senators who expressed themselves urged their conferees to insist on the two points in question. On June 23 the conferees were appointed and consisted of Proctor of Vermont, Hansbrough of North Dakota, and Simmons of North Carolina. The House conferees were Wadsworth of New York, Scott of Kansas, and Lamb of Virginia.

Four days later Proctor reported to the Senate that the House conferees positively refused to compromise on the matter of paying for meat inspection. The Senate conferees had proposed a compromise to the effect that the packers should pay into the treasury five cents per head for cattle and three cents for every hog, sheep, and goat that was inspected. (This, it was estimated, would pay about half the actual expense.) But the suggestion had not been accepted.[49] The other controversial point had not been touched upon.

The next day Proctor submitted the conference report on the Agricultural Appropriation Bill. Everything had been agreed upon except the points relating to meat inspection.[50] The Senators urged their conferees not to jeopardize the whole bill on account of those two points, especially since they were not of fundamental importance.

On the same day the question was taken up in the House. Wadsworth moved that the House conferees should not recede from their position. This provoked a lively debate. Over and over it was stated (in both houses) that the packers had brought about the unsanitary conditions in the meat industry and that they should pay for correcting them. Humphrey of Washington delivered himself of the follow-

[45] *Id.* at 542.
[46] 40 CONG. REC. 8763, 9656 (1906).
[47] *Id.* at 8767-9.
[48] *Id.* at 8789.
[49] *Id.* at 9019.
[50] *Id.* at 9076-8.

ing philippic: "The most loathsome and slimy criminal that curses the earth is the one that adulterates food." He is a "fiendish monster." "If I could call from the 'lowest depths of hell words so hot that I could construct out of them sentences that would writhe and hiss like the fanged and poisonous serpent,' I could not express my horror, my loathing, and my hate for those merciless fiends who, for the dollar, traffic in human health and human life, who poison and destroy and murder the helpless and unsuspecting victims that they have already robbed. . . . Honesty and decency stand stupified before the effrontery of the demands of these criminals—that the people pay the cost of the inspection. What is their proposition? That the people shall pay to have them stop their filthy and dangerous practices; that the people shall pay to compel them to obey the law; that the people shall pay to stop them from defrauding and robbing the public; that the people shall pay to prevent them from destroying life and spreading disease; that the people shall pay to stop them from poisoning and murdering the innocent and helpless! A proposition more monstrous never came from the polluted lips of crime."[51] Nevertheless, the motion carried by a vote of 193 to 45.

On June 29 the Senate gave way and the conference report was adopted by both houses. In the Senate there was considerable bitterness. Proctor said he had never seen "such open and bare-faced use" of the method of trying to influence Congress by flooding it with telegrams from all over the West, in identical language, "all evidently emanating from Chicago."[52] Nelson claimed that three things had been sought: (1) to placate the packers; (2) to placate the range-cattle men; (3) to get a good market for packers abroad. "I feel," he said, "as though when I go home I will go home like a licked dog, whipped by the packers and by the raisers of range cattle, and nobody else."[53] McCumber thought the whole great conflict could be epitomized in a few words: "We have met the enemy and we are theirs—indemnity, $3,000,000."[54]

On the same day that the pure food and drugs bill was signed, June 30, 1906, the agricultural appropriation bill, of which the meat inspection rider was a part, received the presidential signature.[55] The former went into effect on January 1, 1907, the latter, on July 1, 1906; and a struggle which for many years had been waged in the legislative arena was transferred to the field of administrative action.[56]

[51] *Id.* at 9470-2.
[52] *Id.* at 9573.
[53] *Id.* at 9656.
[54] *Id.* at 9658.
[55] *Id.* at 9660.
[56] It might be added that there had been a very decided decrease in the adulteration of food before June, 1906, because of the vigorous enforcement of the state pure-food laws.

THE ADMINISTRATION OF THE FEDERAL FOOD AND DRUGS ACT*

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I

Three factors combine to make the enforcement of the Federal Food and Drugs Act of 1906 an administrative problem of peculiar difficulty. These factors are, first, the nature of the offenses defined by the Act; second, the character of the industries affected; and, finally, the limitations inherent in all federal action under the commerce clause. A brief, preliminary consideration of the effect of each of these three factors may throw light on the development of the administrative machinery set up under that Act.

The Act forbids interstate commerce in adulterated and misbranded food and drugs. It provides criminal penalties for violation and also authorizes the seizure of offending products.[1] In the case of standard drugs, the United States Pharmacopoeia and the National Formulary were resorted to by Congress for the purpose of establishing standards of purity and quality which the drug manufacturers were enjoined to follow—unless they declared standards of their own on the labels of their products. In that event, their own standards afforded the criteria to which they were obliged to conform.[2] In the case of foods, standards were not available, and in their stead, the draftsmen of the Act resorted to generalities proscribing the intermixture or substitution of substances reducing quality, the abstraction of valuable constituents, the concealment of damage or inferiority, the addition of deleterious ingredients, and the use of spoiled animal or vegetable products.[3] Misbranding was confined chiefly to

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[1] Section 2 of the Act imposes for a first offense a fine not exceeding $200; for each subsequent offense, a fine not exceeding $300 or imprisonment not exceeding one year or both, in the discretion of the court. 34 Stat. 768 (1906), 21 U. S. C. A. §2. Somewhat higher penalties are provided for manufacture in the District of Columbia and the territories. *Ibid.* The seizure provisions are contained in §10. 34 STAT. 771 (1906), 21 U. S. C. A. §14.

[2] F. & D. ACT, §7, 34 STAT. 769 (1906), 21 U. S. C. A. §8.

[3] *Id.*

the making of false or misleading statements regarding a food or drug on the package or label thereof.[4] The sale of an imitation was forbidden, but this was accompanied by provisos which relieved mixtures or compounds not in themselves harmful when sold under "their own distinctive names" or when labeled with the word "compound," "imitation" or "blend," from the operation of both the misbranding and adulteration provisions of the Act.[5] Aside from the latter, the only affirmative labeling requirements were the disclosure of the presence and quantity of enumerated narcotic drugs[6] and the declaration of the net weight of foods when sold in package form.[7]

It is obvious, of course, that the detection of offenses of this character calls for scientific work of a high order. Difficulty of detection is, however, all too commonly encountered in law enforcement. But the Food and Drugs Act does not make plain what constitutes an offense. What amount of moisture in oats or fresh water in oysters constitutes adulteration? Some is present in all.[8] When does "whiskey" become "imitation whiskey," to take as an example a problem which once perplexed the Bureau of Chemistry and whose ghost is beginning to walk. Ultimately the answers to these questions must be resolved by the courts, but obviously they must first be determined by the enforcement officials as a preliminary to action.

The magnitude of the food and drug industries, estimated recently as producing goods valued at twenty billion, furnishes an enforcement problem whose seriousness is greatly intensified by the fact that these industries are decentralized, not only as to distribution, which is inevitable, but as to production as well. The emergence of large corporations engaged in processing and distribution is a relatively recent and limited phenomenon; and even this tendency has not materially simplified the problem of enforcement, for the production units are still small and scattered. Fruits and vegetables are usually canned near the source of supply. The same label may be affixed to the products of a hundred canneries. Uniformity as to product and conditions of manufacture can, at best, be only approximate.

To this difficulty must be added the related one which springs from the diversity of products affected. A single drug house publishes a catalog containing fifteen

[4] The misbranding provisions of the original Act are contained in §8. 34 STAT. 771 (1906). They are set forth with amendments in 21 U. S. C. A. §§9, 10.

[5] This immunity does not extend to the presence of added poisonous or deleterious ingredients. See F. & D. ACT, §9, 21 U. S. C. A. §10.

[6] The list of drugs comprises "morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide or any derivative or preparation of any such substances contained therein." F. & D. ACT, §8, 21 U. S. C. A. § 10. The enumeration has been found not to be sufficiently comprehensive.

[7] F. & D. ACT, §8, 21 U. S. C. A. §7. Provision is made for reasonable variations, tolerances, and exemptions as to small packages, to be established by rules and regulations. This clause was recently construed by the United States Supreme Court in United States v. Shreveport Grain & Elevator Co., 287 U. S. 77 (1932).

[8] These questions were recently litigated in United States v. 800 Sacks Barley Mixed Oats, 64 F. (2d) 678 (C. C. A. 5th, 1933) and, to cite but one of numerous cases involving this form of oyster adulteration, United States v. Housman Oyster Co., Not. Judg. 19307 (S. D. N. Y., 1932).

hundred pages. Most large food corporations produce more than "57 varieties," including the company which fixed that phrase in the national consciousness.

The third factor, the limitations of federal control, is magnified in importance by the second. The Food and Drugs Act, except in so far as its provisions relate to the District of Columbia and the territories, is based on the power of Congress over interstate and foreign commerce. Only those products entering such commerce are within its purview. The necessity for proof of interstate shipment precludes concentration of enforcement activities at the source. The "original package" doctrine draws an often indistinct line beyond which federal enforcement may not go in the state of distribution. Only in the case of imports is federal control relatively simple.[9]

II

Research in food adulteration had been undertaken by Dr. Harvey W. Wiley, Chief of the Chemical Division of the Department of Agriculture, as early as 1883.[10] The revelations were alarming. These studies, coupled with his unremitting efforts on behalf of pure food legislation, rendered it inevitable that the work of enforcement should be vested by the Food and Drugs Act in that Department. The Bureau of Chemistry, into which the Chemical Division had been transformed, continued in this rôle until July 1, 1927. Its activities were not, of course, confined to this work, and the desirability of divorcing its agricultural research from its regulatory activities led to the creation then of the Bureau of Chemistry and Soils to undertake the former and the Food, Drug, and Insecticide Administration to carry on the latter.[11] The Appropriation Act for the Department of Agriculture for 1930 provided funds for the *Food and Drug Administration,* thereby shortening the name of the regulatory branch without affecting the scope of its activities.[12]

[9] Section 11 provides that the Secretary of the Treasury shall deliver to the Secretary of Agriculture samples of foods and drugs being imported upon the giving of notice to the consignee. The article shall be refused admission if found upon examination to be adulterated or misbranded. Such articles must be destroyed or re-exported within three months, although delivery to the consignee pending examination may be made on the execution of a penal bond. 21 U. S. C. A. §15.

It should be noted that this section contemplates administrative and not judicial action for its enforcement.

[10] See WEBER, FOOD, DRUG, AND INSECTICIDE ADMINISTRATION (1928) 2.

[11] Department of Agriculture Act of Jan. 18, 1927, 44 STAT. 1002-1003. The basis for this distinction is described in the Report of the Chief of the Bureau of Chemistry as follows:

"Research and regulatory work demand the attention of officials of entirely different qualifications. The regulatory chemist, because of the detriment of delayed decisions to industry and commerce, is obliged to form his conclusions quickly, although in some cases these decisions may be wrong. The research chemist, on the other hand, must form his conclusions with more deliberation because of the necessity of verifying his work by all the possible checks at his disposal. The regulatory chemist, owing to the demands of law enforcement, limits his attention to the small percentage of products which constitute infractions of certain State or Federal enactments and ignores the vastly larger percentage of products which meet the requirements of those acts. The research chemist, on the other hand, is concerned more with the rendering of service to industries whose products are of the latter class." REP. CH. BUR. CHEM. (1927) 3.

[12] 46 STAT. 423 (1930). In addition to the Food and Drugs Act, the Administration is charged with the enforcement of the following statutes: The Caustic Poison Act, 44 STAT. 1406 (1927); the Insecticide

The geographical decentralization of the food and drug trade has dictated a degree of decentralization in the organization of the Administration. The country is divided into three districts: the Eastern, with headquarters at New York City; the Central, with headquarters at Chicago; and the Western, with headquarters at San Francisco.[13] Within each district are several inspection stations and laboratories,[14] the duties of which include the collection and analysis of samples of articles subject to the regulatory acts enforced by the Administration, and other investigational and administrative work in connection therewith. Each of the inspection stations has a station chief in charge, and inspectors, chemists and a clerical force. In the Administration's 1929 Report, it is stated that the "field laboratories as a whole have been equipped so that samples of all kinds of products can be analyzed in any one of a number of laboratories. Inspectors have been trained to sample any or all of the commodities covered by the six laws assigned to the administration." Immediate supervision over the inspection station is exercised by the chief of the district within which it is located. Above the district chiefs in the hierarchy is the Chief of the Food and Drug Administration, with offices at Washington.[15] Ultimate authority is in the Secretary of Agriculture, as head of his Department.

The members of the Administration are appointed by the Secretary of Agriculture, under civil service regulations—a six months' temporary appointment, which becomes permanent at the termination of the probationary period. The power to remove also is vested in the Secretary of Agriculture, restricted by civil service rules to removal only for cause. The small size of the personnel has made careful selection possible and contributed to the development of an admirable *esprit de corps*. Resort to disciplinary action has seldom been required.

Act, 36 STAT. 331 (1910); The Milk Act, 44 STAT. 1101 (1927); the Naval Stores Act, 42 STAT. 1435 (1923); and the Tea Act, 29 STAT. 604 (1897); 35 STAT. 163 (1908).

The Tea Act was administered by the Secretary of the Treasury until July 1, 1920, when its enforcement was transferred from the Customs Division of the Department of the Treasury to the Bureau of Chemistry of the Department of Agriculture. 41 STAT. 712 (1920).

[13] The Eastern district comprises the New England States, New York, New Jersey, Pennsylvania, Delaware, Maryland, Virginia, West Virginia, North Carolina, South Carolina, Georgia, and Florida; the Central district, Ohio, Kentucky, Tennessee, Alabama, Mississippi, Louisiana, Indiana, Missouri, Michigan, Minnesota, Wisconsin, North Dakota, South Dakota, Iowa, Illinois, Kansas, Arkansas, Oklahoma, Texas, and Nebraska; and the Western district, Montana, Wyoming, Idaho, Nevada, Utah, Colorado, New Mexico, Arizona, Washington, Oregon, and California.

[14] Inspection stations and laboratories for the Eastern district are located at Baltimore, Boston, New York City, Philadelphia, Rouse's Point, N. Y., San Juan, P. R., and Savannah; for the Central district, at Chicago, Cincinnati, Kansas City, Mo., Minneapolis, New Orleans, and St. Louis; and for the Western district at Denver, Los Angeles, Seattle, and San Francisco.

There is a complete outline of the personnel of the Administration as of the date of writing in WEBER, THE FOOD, DRUG, AND INSECTICIDE ADMINISTRATION, ITS HISTORY, ACTIVITIES AND ORGANIZATION (1928). This work, No. 50 of the Service Monographs of the United States Government published by the Institute for Government Research, contains the most comprehensive study available of the organization of the Administration.

[15] The Washington offices of the Food and Drug Administration include the following subdivisions: Interstate Supervision, Import Supervision, State and City Coöperation, Food Control, Microanalytical Laboratory, Color Certification, Drug Control, Special Collaborative Investigations, Insecticide Control and Naval Stores Control. See inside cover of DEPT. AGR. MISC. CIRC. No. 48 (1930).

III

The Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce are charged by the statute with the duty of promulgating rules and regulations for the enforcement of the Act.[16] After the enactment of the law of June 30, 1906, a committee of three was chosen, one member appointed by each of the three secretaries, for the purpose of drawing up rules and regulations.[17] Hearings were held by the committee in order to make certain that the rules promulgated might not burden unnecessarily the industries affected. The rules and regulations formulated by the committee were issued over the signatures of the three secretaries on October 17, 1906, as a circular of the Department of Agriculture.[18] They have been revised from time to time as the Act has been interpreted by court decisions and as experience has shown to be necessary and are now in the tenth revision.[19]

These rules and regulations have the force of law so long as they are administrative of the law and do not attempt to add to its terms.[20] Supplementary to them as guides to the public and to food and drug manufacturers are the notices of the judgments reached in all cases which are published after their termination,[21] and food inspection decisions issued from time to time over the signature of the Secretary of Agriculture prescribing standards which the Administration feels should govern in the determination of questions of purity and quality. The position of the Department with respect to these decisions was formulated in 1906 as follows:

> The opinions or decisions of this Department do not add anything to the rules and regulations nor take anything away from them. They therefore are not to be considered in the light of rules and regulations. On the other hand, the decisions and opinions referred to express the attitude of this Department in relation to the interpretation of the law and the rules and regulations, and they are published for the information of the officials of the Department who may be charged with the execution of the law and especially to acquaint manufacturers, jobbers, and dealers with the attitude of this Department in these matters. They are therefore issued more in an advisory than in a mandatory spirit. It is clear that if the manufacturers, jobbers, and dealers interpret the rules and regulations in the same manner as they are interpreted by this Department, and follow that interpretation in their

[16] See F. & D. ACT, §3, 21 U. S. C. A. §3.

[17] The committee consisted of H. W. Wiley, Chief of the Bureau of Chemistry; S. N. D. North, Director of the Census Bureau of the Department of Commerce and Labor; and James L. Gerry, Chief of the Division of Customs of the Treasury Department. YEARBOOK, DEPT. AGR. (1907) 70. There is an account of the work of this committee in WILEY, HISTORY OF A CRIME AGAINST THE FOOD LAW (1929) 78 *et seq.*

[18] Circular No. 21. See YEARBOOK, DEPT. AGR. (1907) 70.

[19] Regulations for the Enforcement of the Federal Food and Drugs Act (Tenth Revision, 1930). Service and Regulatory Announcements, Food and Drug No. 1. These regulations are identical in substance with those of the Ninth Revision.

[20] United States v. Antikamnia Chemical Co., 231 U. S. 654 (1914). In one instance a member dissented; the regulation as to the use of saccharin in foods was signed by the Secretary of Agriculture and the Secretary of Commerce and Labor, the Secretary of the Treasury dissenting. It was thereupon issued as a *food inspection decision*, (FOOD INS. DEC. 142 (1912), over the signature of Secretary of Agriculture, thereby becoming merely a departmental guide.

[21] Section 11 of the Act requires the publication of these notices. 19,900 had been published as of April 14, 1933.

business transactions, no prosecution will lie against them. . . . It may often occur that the opinion of this Department is not that of the manufacturer, jobber, or dealer. In this case there is no obligation resting upon the manufacturer, jobber, or dealer to follow the line of procedure marked out or indicated by the opinion of this Department. Each one is entitled to his own opinion and interpretation and to assume the responsibility of acting in harmony therewith. . . .[22]

The Department began in 1914 the publication of both the notices of judgment and the food inspection decisions in a single series of pamphlets captioned "Service and Regulatory Announcements." The last food inspection decision was issued June 10, 1927; "Definitions and Standards for Food Products," and "Regulatory Announcements" are now published in their stead. The change is for all practical purposes one of terminology only.

In 1907, the Secretary of Agriculture appointed a Board of Food and Drug Inspection, the duties of which were to consider the questions arising in the early days of the enforcement of the new Food and Drugs Act upon which the decision of the Secretary of Agriculture was necessary, and to conduct hearings upon alleged violations of the law. They also considered and supervised the voluminous correspondence occasioned by the new law, most of which involved interpretations. The Board was necessarily merely advisory in character, and its action required the approval of the Secretary of Agriculture. In 1915 this Board was abolished.

The Food Standards Committee, which is still functioning, was appointed in 1914, following a conference called by the Secretary of Agriculture in 1912. This committee of nine members appointed by the Secretary of Agriculture—three from the federal Food and Drug Administration, three from the Association of American Dairy, Food and Drug Officials, and three from the Association of Official Agricultural Chemists—has for its purpose the formulation of standards to be adopted by both federal and state agencies with a view to attaining uniformity in action.[23] The committee meets at irregular intervals, and hearings are held at which manufacturers and other interested parties may present their views on matters under consideration. When the standards are prepared, they are submitted to the various states for adoption; and following the approval of the states, they are issued over the signature of the Secretary of Agriculture as a regulatory announcement.

Through the Office of Coöperation, also established in 1914, the collaboration of the state with federal food and drug enforcement has been greatly furthered.[24] State

[22] FOOD INS. DEC. 44 (1906).

[23] Following the enactment of the federal legislation in 1906, state legislation, similar in most respects to the federal statute, was enacted very generally. For a description of this legislation, see THORNTON, THE LAW OF PURE FOOD AND DRUGS, NATIONAL AND STATE (1912).

[24] "The Bureau of Chemistry's Office of State Control [now the Office of Coöperation of the Food and Drug Administration] is essentially a State agency in a Federal bureau. It is a special agent for the State or municipal official. It acts as a clearing house for all matters dealing with food and drug control, so that all the officials of the country may be kept informed upon all that is in progress throughout the country. It furnishes regularly information and assistance to State and municipal officials. The result is that Federal, State and municipal officials are able to supplement each other more effectively than was

and city enforcement officials are commissioned by the Secretary of Agriculture and, when a violation of the law is discovered, may cause proceedings to be instituted under the federal law if federal action is indicated. At the same time, federal officials upon the discovery of illegality may turn over the case for state action. Especially is this done in instances in which evidence of the interstate character of the shipment is not conclusive. State prosecution is relied upon also in a great many cases in which proceedings might be brought under either federal or state law, as a method of stretching to the greatest possible extreme the limited amount of money at the disposal of the federal agency.

Through these two agencies, the Food Standards Committee and the Office of Coöperation, "independent and conflicting action by independent groups of officials is, to a large extent, voluntarily obviated."[25]

IV

The fact that, subject to judicial sanction, the determination of what conduct constitutes an offense under the Act lies in considerable measure in the judgment of the Administration gives to its decisions of policy an exceptional significance. Primarily this responsibility rests upon the Chief of the Administration; ultimately, upon the Secretary of Agriculture. It is difficult to determine to what extent the Secretary of Agriculture exercises his potential power of control of the Food and Drug Administration. Whether any Secretary has ever refused to sanction a prosecution recommended by a subordinate official cannot be ascertained. During the first year or so of the enforcement of the Act the hearings afforded to persons accused of violation were sometimes conducted by the Secretary himself.[26] This seems not to be the case today.

As to control of administrative action through indirect means, here again what goes on "behind the scenes" seldom becomes public knowledge except when internal disagreement assumes large proportions. The classic instance of dissension is that of Dr. Harvey W. Wiley, the then Chief of the Bureau of Chemistry and one of the draftsmen of the Act, with Secretary of Agriculture James Wilson and President Theodore Roosevelt, a struggle which lasted for several years and which culminated in Dr. Wiley's resignation in 1912.

When some manufacturers sought relaxation of Dr. Wiley's crusade against preservatives in foods, they found him adamant and relentless in his attitude. Control of his zeal was had indirectly through executive appointment of boards and committees. At the instance of President Roosevelt, the Secretary of Agriculture appointed a Board of Food and Drug Inspection to pass upon all the decisions of the

possible early in the law's enforcement." Alsberg, *Ten Years of the Food and Drugs Act*, REP. SEC. AGR. (1917) 210, 211.

[25] Alsberg, *supra* note 24, at 211. See also Conover, *National, State and Local Coöperation in Food and Drug Control* (1928) 22 AM. POL. SCI. REV. 910, 923 *et seq.*

[26] See Bigelow, DETAIL OF THE ENFORCEMENT OF THE FOOD AND DRUGS ACT, YEARBOOK, DEPT. AGR. (1907), at 327.

Bureau of Chemistry and to conduct the hearings of alleged violators of the law. The committee consisted of Dr. Wiley and an Assistant Chief Chemist (who took no orders from the Chief) and the Solicitor of the Department of Agriculture. Since any action of the board required a majority vote, the other two members could effectually nullify Dr. Wiley's authority.

The creation of another board came about also as the result of the opposition of certain manufacturers to the ideas of Dr. Wiley, especially as to the use of chemical preservatives. It, too, was appointed by the Secretary of Agriculture acting under orders from President Roosevelt. By means of the Referee Board of Consulting Scientific Experts (usually referred to as the Remsen Board, taking its name from its chairman) even more complete control of Dr. Wiley was effected. The ostensible purpose, at least, of the Board was "to give the Secretary the benefit of the disinterested and unbiased advice of eminent and expert chemists when a serious conflict of opinion should arise as to the deleteriousness of any particular article or substance added to foods."[27] The recommendations of the Remsen Board were accepted by the Secretary of Agriculture and used by him in the preparation of departmental guides for enforcement of the Act. On the basis of its recommendations, food inspection decisions allowing the use of small quantities of benzoate of soda, sulphur dioxide, and alum were promulgated.[28] Dr. Wiley's opposition to the use of these substances ended only with his death.[29]

The Secretary of Agriculture has, of course, ample opportunity to influence the enforcement of the Act through his control over the issuance of regulatory announcements defining the Administration's attitude. Dr. Wiley has said that Secretary Wilson refused to permit the publication and issuance of certain monographs and studies on foods and drugs, and charged further that the Secretary forbade the publication of a bulletin on benzoic acid which through error was printed but which the Secretary refused to allow to be reprinted.[30]

More recently, a regulatory announcement issued by the Secretary of Agriculture completely reversed the policy of the Food and Drug Administration with respect to the use of corn sugar in foods. Early food inspection decisions required that foods containing corn starch be so labeled,[31] and the term "sugar" was restricted to sucrose.[32] Legislation designed to permit the freer use of corn sugar has been before Congress on more than one occasion but has consistently failed to pass. A

[27] Weber, *op. cit., supra* note 15, at 18-19. The legality of the Referee Board never came before the courts. It was disputed vigorously in the press of the day, see *e.g., Fight on Dr. Wiley and Pure Food Law* (1922) 22 WORLD'S WORK 14787; Dunn, *Dr. Wiley and Pure Food* (1911) 22 WORLD'S WORK 14958. However, it was upheld in an opinion of the Attorney-General. 27 OP. ATTY. GEN. 300 (1909).

[28] See FOOD INS. DECS. 76, 89, 101, 104.

[29] On the subject of appointment of the Board of Food and Drug Inspection and the Referee Board, see *Fight on Dr. Wiley and Pure Food Law, supra* note 27; Bjorkman, *Our Debt to Dr. Wiley* (Jan. 1910) 19 WORLD'S WORK 12443; WILEY, AN AUTOBIOGRAPHY (1930) 237 *et seq.*; WILEY, HISTORY OF A CRIME (1929) *passim;* 43 CONG. REC. 1360 (1909).

[30] WILEY, HISTORY OF A CRIME (1929) 62.

[31] REG. ANN. 4 (1914).

[32] FOOD INS. DEC. 66 (1907).

bill to permit its use in bakery and confectionery products was killed by a filibuster in the Senate, after having first been passed in the Senate and then amended in the House.[33] In 1930, a bill to define and set standards for fruit preserves, jams, jellies, etc., which was introduced in Congress provided that these products should contain a certain quantity of fruit and a set percentage of "any kind of refiner's sugar."[34] The bill was opposed by the Chief of the Food and Drug Administration on the ground that it permitted the manufacturer to use corn sugar without indicating its presence on the label of the product and on the broader ground that the public should be apprised of the contents of the food they buy. The Chief appeared at the hearing before the House Committee to which the bill was referred and offered amendments to overcome his objection.[35] The bill, opposed by some manufacturers and approved by others, was never reported out of committee, so that the position of corn sugar remained *in statu quo.*

On December 26, 1930, over the signature of the then Secretary of Agriculture, the following regulatory announcement was issued:

> Corn sugar (dextrose) when sold in packages must be labelled as such; when sold in bulk must be declared as such; but the use of pure, refined corn sugar as an ingredient in the packing, preparation, or processing of any article of food in which sugar is a recognized element need not be declared upon the label of any such product. . . . The term "sugar," with or without the parenthetical expression "sucrose" as used in the definitions to designate the sweetening agent in manufactured food products, is to be interpreted, wherever necessary to effect the purpose of the foregoing decision, as including dextrose (pure, refined corn sugar).[36]

In the absence of some quarrel of the magnitude of Dr. Wiley's, the reasons behind the change of policy in regard to dextrose will probably never be made public.

V

Congress has, of course, no direct control over the activities of the Administration aside from its power to amend the Act. However, several very effective means of indirect control are at its disposal. The appropriations granted to the Department of Agriculture for the use of the Food and Drug Administration may greatly influence the scope of enforcement.[37] The Administration has frequently commented

[33] 69th Cong., 1st Sess., S. 481 (1926). See 67 CONG. REC. 3011; 11317; 11332; 11463; 11511; 11512; 12102; 12305; 12361; 12473; 12478 (1926).

[34] 71st Cong., 2nd Sess., H. RES. 9760 (1930).

[35] Hearings before the House Committee on Agriculture on H. R. 9760, 71st Cong., 2nd Sess. (1930) 28 (Standards for Fruit Jams, Fruit Preserves, Fruit Jellies, and Apple Butter).

[36] Service and Regulatory Announcement, F. D. 2, REV. 1, Supp. 3.

[37] Beginning in 1909, which is the first year in which the appropriations were made specifically for the purpose of enforcing the Food and Drugs Act and not embodied in the general appropriation for the Bureau of Chemistry, the amounts granted by Congress have been:

1909	$ 685,460.00	1912	$ 625,000.00	1915	$ 635,161.00
1910	702,340.00	1913	675,000.00	1916	632,951.00
1911	610,110.00	1914	644,301.00	1917	623,521.00

upon the inadequacy of available funds; and its "project system" of enforcement, discussed below, is in some measure the result of an effort to obtain the greatest results possible with the limited means at hand.[38] The increase in the number of prosecutions carried on in 1932 has been attributed by the Chief of the Administration directly to the increased budget for that year.

Congressional investigations of the enforcement of the Food and Drugs Act have been largely tempests in teapots from which little if any action or alteration has resulted. In 1910, resolutions were adopted, requesting from the Secretaries of Commerce and Labor, Agriculture, and the Treasury, and the Attorney-General, information as to whether the enforcement of the Food and Drugs Act had been suspended or specific persons exempted from its provisions.[39] The Secretary of Agriculture replied that no order had been issued suspending the operation of the Act and that no individual had been granted immunity. The other replies were of the same tenor.[40]

The House hearings on the Expenditures in Agriculture Department in 1911 developed into a general investigation of the intradepartmental operation of the Bureau of Chemistry, then charged with the enforcement of the act. An unofficial Senate hearing on the administration of the Act in 1930 resulted in no changes.[41]

Needless to say, individual congressmen frequently confer with the officials of the Administration in Washington on behalf of aggrieved constituents, a process which results more generally in the enlightenment of the congressman than in benefit to the complainant. Occasionally, where regional interests are involved, representations will be made to the Secretary of Agriculture himself. Representatives from the northwestern states have been especially active in recent years on behalf of the fruit growers of that section who felt the burden of the Administration's regulations against the lead and arsenic residues of insecticides remaining on sprayed fruits.

VI

The "project" system of enforcement in use for many years is a system of organization of effort. With the realization that it is for all practical purposes impossible to put an end to all adulteration and misbranding of foods and drugs in interstate commerce, the activities of the Administration are centered upon those articles in widest use and most apt to affect great numbers of people—in other words,

1918	$ 589,801.00	1923	$ 704,401.00	1928	$ 938,000.00
1919	620,221.00	1924	716,260.00	1929	1,030,000.00
1920	579,361.00	1925	788,860.00	1930	1,125,000.00
1921	671,401.00	1926	785,408.00	1931	1,315,865.00
1922	671,401.00	1927	918,780.00		

[38] See *e.g.* REP. F. D. AND I. ADM. (1930) *passim;* Hearings on the Administration of the Federal Food and Drugs Act, 71st Cong., 2nd Sess. (1930) 212.

[39] 61st Cong., 1st Sess., H. RES., 66-69 (1909).

[40] 45 CONG. REC. 412 (1910).

[41] An account and an interpretation of this hearing (which lasted from February 12, 1930 to June 30, 1930) may be found in *History of the Ergot Investigation* (1930) 95 AM. MED. ASSN. J. 722.

upon staple products.[42] The Administration proceeds upon the theory that most manufacturers are doing a legitimate business and wish to remain within the law. Ordinarily, an isolated violation of the law, unless flagrant and obviously premeditated, is not proceeded against until the violator has been given warning and an opportunity to bring his product into conformity with the law.[43] But when advisory methods fail and more severe treatment is required, resort to the courts must be had.

Upon the basis of factory inspections and analysis when necessary, the Administration determines what particular food and drug products are being adulterated or misbranded and what types of violations may be expected during the ensuing year. The comparatively small section of an industry which is doing a questionable business is thereby segregated from the other sections. Thus the field of possible activity is narrowed with respect both to kinds of commodities and to manufacturers of those commodities and the activities of the Administration are directed toward controlling the smaller field rather than proceeding haphazardly against the mass of products in interstate commerce. Plans for the enforcement of the law in a uniform manner throughout the country are formulated at the beginning of each year. The system is kept flexible, however, so that in the event of an emergency such as an outbreak of food poisonings, the forces may be directed toward investigation of the problems connected therewith.

In the actual enforcement the problem of detection is complicated by the limitations of federal authority. The first step in the procedure for the punishment of suspected violations is the collection of samples,[44] a matter in itself somewhat complex. The specimens must be taken in such a manner that the interstate character of the shipment which was sampled can be shown, and detailed instructions are issued describing all the various pieces of information which must be obtained in order properly to prove interstate shipment.[45]

The sample, with all the accompanying data as to mode and place of collection, interstate shipment, etc., is forwarded to the nearest inspection station, where it is

[42] See REP. CH. CHEM., Dept. Agr. (1924) 18. The Administration has said:

". . . the entire personnel and appropriation granted for the law-enforcement work could be utilized annually in a meticulous supervision of the interstate and import traffic in one or two staple commodities. It has been estimated, for example, that a thorough sampling and analysis of every interstate shipment of two such staple commodities as flour and butter would more than absorb the entire annual appropriation for the enforcement of the law. . . ." REP. F. D. AND I. ADM. (1930) 3.

[43] "It is believed that more effective compliance with the law may be obtained by showing reputable manufacturers how to bring their products into conformity with its terms than by imposing fines or effecting seizures and confiscations after the violation has been committed. Its policy, therefore, is to pursue educational methods as a preliminary to legal action where this can be done without jeopardizing the public interest or legitimate competitive conditions." REP. F. D. AND I. ADM. (1926) 20.

[44] Three specimens are taken. "Upon request one subdivision [of the sample] if available shall be delivered to the party or parties interested." Reg. 3.

[45] See MANUAL OF PROCEDURE FOR GUIDANCE OF CITY AND STATE HEALTH, FOOD AND DRUG OFFICIALS (Dept. Agr. 1919). Although this pamphlet is issued primarily for the use of coöperative officials, the sampling procedure is the same.

analyzed.[46] If the analysis shows adulteration or misbranding within the Administration's understanding of those terms, and if the station chief considers the case appropriate for prosecution proceedings, the results of the analysis, together with the recommendation for criminal prosecution, are sent by the station chief to the district chief. The district chief considers the recommendation and, if he approves, instructs the inspection station to cite the manufacturer or shipper or dealer from whom the sample was procured to a hearing at the station headquarters. At the same time the district chief submits a statement of the action taken to the Chief of the Administration in Washington.

Section 4 of the Act requires a hearing as a prerequisite to action by the Administration where criminal prosecution is contemplated. It is not, however, a prerequisite to independent action by a district attorney,[47] nor is it required in the case of seizure proceedings[48] where time may frequently be of the essence. The hearing is not a judicial proceeding[49] and is for the "purpose of affording the manufacturer, shipper, or dealer an opportunity to show that an error has been made in either the collection or analysis of the sample or the interpretation of the results. He may also produce evidence of a guaranty from the person from whom he obtained the consignment of which the sample is a part."[50]

On the date set for hearing, the person cited may report in person or by attorney for an oral hearing, or he may present his statement in writing as to why the government should not take further action, or, if he choose, he may remain silent. There is no method of compelling his attendance or the transmittal of written statements. If the person cited appears for an oral hearing, the proceedings are conducted by a member of the Administration, usually the station chief. After the hearing, if there has been one, or after the date set for the hearing if the person cited has chosen to remain silent, the station chief sends to the district chief a recommendation as to the proper course to be pursued. If there was a hearing, the station chief's summary of the findings is forwarded with the recommendation. The district chief may indorse the station chief's recommendation or he may modify it. In either event he sends

[46] Bigelow, *supra* note 26, at 321 *et seq.*, and Dept. Agr. Misc. Pub. No. 48 (Supp. 1930) have been largely relied upon for the following account of procedure. See also Wharton, *Requirements of the Federal Food and Drug Act*, 20 AM. FOOD J. 461 (1925); Dunbar, *Enforcement of Food and Drugs Act*, 110 OIL, PAINT AND DRUG REPORTER (Nov. 1, 1926) 22.

[47] United States v. Morgan, 222 U. S. 274 (1911).

[48] This has been the practice since the beginning. See Bigelow, *supra* note 26, at 328. The courts have sustained the practice. United States v. Seventy-Five Boxes of Alleged Pepper, 198 Fed. 934 (D. C. N. J. 1912); United States v. W. T. Rawleigh, 57 F. (2d) 505 (C. C. A. 10th, 1932).

[49] ". . . But the hearing is not judicial. There is no provision for compelling the presence of the party from whom the sample was received; if he voluntarily attends he is not in jeopardy; an adverse finding is not binding against him; and a decision in his favor is not an acquittal which prevents a subsequent hearing before the Department, or a trial in court.

"The provision as to hearing is administrative, creating a condition where the district attorney is compelled to prosecute without delay." United States v. Morgan, *supra* note 47 at 281. Notice and hearing are not conditions precedent to prosecution. *Id.*

[50] Bigelow, *supra* note 26, at 327.

all the papers in the case to the office of the Chief of the Administration, with his statement of what he deems the proper action to be taken.

The Chief or Assistant Chief may decide on the next step. As a rule, however, he refers the matter to the laboratory at the central headquarters in Washington which specializes in the product under consideration. If the specialist agrees with the district chief's recommendation for prosecution the case is turned over to the Chief or Assistant Chief with an endorsement of the recommendation. If one of these officials agrees with the recommendation for prosecution, all the papers in the case are examined by the Administration's solicitor in the office of the Solicitor of the Department of Agriculture who decides whether the evidence at hand is sufficient to support criminal prosecution; and if he and the solicitor concur in the Administration's recommendation, he prepares the papers necessary to be transmitted to the Department of Justice.

Where seizure proceedings are contemplated, a more direct procedure is followed. In an instance of a violation of novel impression, the station chief reports the facts and the results of analysis and examination to the central Administration in Washington and institutes seizure proceedings only upon the authorization of the office of the Chief of the Administration. The action in this case, however, serves as a departmental precedent; and if permission to seize has been granted and the seizure has resulted in a decree for condemnation of the offending article, the station chief may proceed on his own initiative against similar articles found in interstate commerce thereafter. As remarked above, no hearing is held.

VII

The procedure thus far considered takes place within the Department of Agriculture, chiefly in the Food and Drug Administration. After collection of specimens, analysis, hearing and recommendations by the various officials concerned, the papers necessary for the Government's case, prepared by the solicitor of the Department of Agriculture, are transmitted to the Department of Justice, from which department the records are sent to the United States Attorney for the district in which the case is to be tried.[51] He may institute criminal proceedings either by indictment or, since violations of the Act fall within the category of "petty offenses," by information.[52] The proceedings in prosecutions for violations of the Act are those of any federal criminal trial. Members of the Food and Drug Administration staff usually appear as witnesses at the trial. In cases involving therapeutic claims, it is usual to supplement their testimony with that of physicians of standing in the community. In an important case, it may be necessary to call upon physicians and scientists of national reputation to serve as expert witnesses.

[51] It has been pointed out by the Assistant Chief of the Administration that there is a review by at least six responsible officers before a case is actually placed before the federal courts for prosecution. Dunbar, *supra* note 46, at 22. This process was severely criticized by Dr. Wiley, who said that the law provides that the Secretary of Agriculture shall decide what action to take, and that there is too much "red tape" in the enforcement of the Food and Drugs Act. Wiley, *Maladministration of the Food and Drugs Act*, 110 OIL, PAINT AND DRUG REPORTER (Nov. 22, 1926) 23.

[52] United States v. J. Lindsay Wells Co., 186 Fed. 248 (W. D. Tenn. 1910).

The alternative to criminal proceedings under the Act, seizure for confiscation by a process of libel for condemnation, authorized by Section 10, is resorted to only in certain classes of cases. These have been outlined by the Administration as follows:

Seizure actions are instituted in four classes of violations:

(1) In the case of food products containing added poisonous or other added deleterious ingredients which may be harmful to health; (2) in the case of food products consisting in whole or in part of filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food, or a product of a diseased animal, or one that has died otherwise than by slaughter; (3) in the case of food or drug products so grossly adulterated or misbranded with false claims that their distribution constitutes a serious imposition upon the public; (4) in the case of deliberate frauds in the shipment of adulterated and misbranded food products which seriously demoralize legitimate trade practices. Unless a violation falls clearly within one of these four classes, seizure action is not taken but the party responsible for the violation may be prosecuted.[53]

Seizure usually precedes the issuance of the libel, but authority is divided whether this is requisite.[54] Any party having an interest in the libeled goods may intervene as claimant. The procedure followed must conform "as near as may be" to the admiralty practice in libel,[55] except that the right of trial by jury of any issue of fact is given both parties. The burden of proof is on the Government, but since the proceeding is not criminal in character, proof need not be "beyond a reasonable doubt," and the Government as well as the claimant enjoys the right of appeal.[56] Products which are condemned as violative of the Act may be ordered destroyed by the court, or, upon the filing of a bond by the claimant conditioned upon the goods being reconditioned so as to meet the provisions of the law, they may be released. The proper disposition to be made is a matter for the discretion of the court.[57]

[53] REP. CH. BUR. CHEM. (1926) 19.

[54] That seizure is not a prerequisite to libel, United States v. Capon Water Co., 30 F. (2d) 300 (D. C. Pa., 1929). *Contra:* United States v. Two Barrels of Dessicated Eggs, 185 Fed. 302 (D. C. Minn., 1911); United States v. Eight Packages and Casks of Drugs, 5 F. (2d) 971 (D. C. Ohio, 1910). The last case also held that verification is necessary. To the contrary is United States v. Eighteen Cases of Tuna Fish, 5 F. (2d) 979 (W. D. Va., 1925) where it is said, at 981: "As has been said, the words 'as near as may be' permit the exercise of a reasonable discretion, and as the delays involved in laying before the court affidavits by persons having first-hand knowledge of the facts may frequently be fatal to the efficacy of the proceeding, I believe it permissible and judicious to order the issue of monitions and attachments on informations which are wholly unsupported by oath or affirmation."

[55] "Section 10 of the act is of very doubtful meaning in several respects; and which of several practices in admiralty was in the mind of the draftsman will, I believe, always be in doubt." McDowell, J., in United States v. Eighteen Cases of Tuna Fish, *supra* note 54, at 981.

Speaking of the words "as near as may be" in connection with their use in the Federal Conformity Act, 17 Stat. 197 (1872), Professor Dobie has characterized them as "the sand in the gearbox, the fly in the ointment, the nigger in the woodpile." Dobie, *Frictional Points of Conflict Between State and Federal Courts,* 19 VA. L. REV. 485, 487 (1933). The same characterization may be made of their use in §10 of the Food and Drugs Act.

[56] Four Hundred and Forty-three Cans of Frozen Egg Product v. United States, 226 U. S. 172 (1912).

[57] United States v. Two Cans of Sweet Birch, etc., 268 Fed. 866 (S. D. N. Y. 1920). In this case, release was denied; the articles were not deleterious but were of low quality and the claimant was a former offender.

Since 1913, the policy has been followed of sending the Department of Agriculture's solicitors to aid in the prosecution of cases brought under the Act. The technical nature of the proof necessary to establish violations renders the assistance of specialists in this type of litigation of great value. Generally, their coöperation has been welcomed, but some United States District Attorneys do not seem to have looked with favor upon the practice. The Administration has never been convinced of the authority of its solicitor to insist upon such participation.[58]

An indirect consequence of the smallness of the penalties provided by the Act is that the local prosecuting officials and trial judges tend to minimize the importance of food and drug cases which, as to first offenses, can result in no more than a $200 fine. Yet their technical character frequently requires thorough preparation, considerable expense in securing expert witnesses, and a full presentation of the Government's case. Such consideration was especially difficult to obtain when the criminal dockets of the federal courts were crowded with cases arising under the Volstead Act.

A source of some conflict between the Departments of Justice and Agriculture lies in the fact that the former determines when an appeal shall be taken, and in some instances it has refused to proceed further in cases where the Food and Drug Administration believed such action to be important. Thus, the Administration favored review of the Bred-Spred case[59] in order to have an authoritative determination of the "distinctive name" proviso of the statute, and of the Lee's "Save the Baby" decision[60] for a ruling on the applicability of the Sherley Amendment, which covers statements of therapeutic claims, to circulars packed with the carton but not physically a part of the label; but the Department of Justice thought otherwise.[61]

VIII

The necessity of judicial action for enforcement of the Act in each contested case[62] is an important limitation upon the activities of the Administration. Yet probably the establishment of a commission to take *quasi-judicial* action in the first instance, subject only to judicial review, is not a practicable alternative. To require hearings in Washington for the minor violations occurring throughout the country would subject defendants to an intolerable burden. Nevertheless, the requirement of a court trial in each contested case has undoubtedly handicapped enforcement.

The generality of the definitions of offenses in the Act is, as has been observed, a source of much difficulty. Each case must stand upon its own factual situation. Interpretation of these definitions by the court is required in virtually every case, although there are instances to be found in which the question of adulteration or

[58] Hearings before the Committee on Agriculture, *supra* note 35, at 199 on H. R. 9760.

[59] United States v. Ten Cases, More or Less, Bred-Spred, 49 F. (2d) 87 (C. C. A. 8th, 1931).

[60] United States v. Certain Bottles of Lee's Save the Baby, 37 F. (2d) 137 (D. C. Conn., 1929).

[61] See REP. CH. F. & D. ADM. (1931) 4.

[62] This requirement is relaxed only with respect to imports. Goods offered for entry but found to violate the law are merely refused entry and destroyed if the owner fails to export or destroy them within 30 days. F. & D. Act §11, 21 U. S. C. A. §15. Regulation 29 deals minutely with import procedure, bonds for release, for reconditioning, etc.

misbranding was determined by analogy to previous cases.[63] There have been but relatively few cases involving the interpretation of the Act which have reached the Supreme Court, and the decisions in the lower federal courts are oftentimes conflicting. On some points, the different circuits are at variance;[64] in at least one instance, the decisions within a single circuit are not uniform.[65] The determination of the interstate character of a shipment and the application of the "original package" doctrine have increased the scope of judicial control. In general, it may be said, however, that the interpretation of the statute has been in the furtherance of its purposes. An egregious exception was the decision of the Supreme Court that therapeutic claims were not included within the scope of the original provision against misbranding.[66] This decision led to the enactment, upon the recommendation of President Taft, of the Sherley Amendment prohibiting "false and fraudulent" claims of this character.[67]

The requirement of trial by jury, which was extended to seizure cases probably to obviate the risk of unconstitutionality, has not infrequently hampered the work of the enforcement officials. Of one hundred seventy-four notices of judgment published March 25, 1933, forty-four followed prosecutions. In the four of these in which pleas of not guilty were entered, there were three jury trials. In each of them the verdict was not guilty.

The technical character of the issues submitted to the jury will often make difficult an intelligent determination of the questions raised. What are the proper ingredients of macaroons?[68] Is caffeine added to a food product a deleterious ingredient?[69] These are not questions for the "man on the street," yet, when the evidence is conflicting, they must be left to the jury. Again, it is reasonable to assume that local juries will sometimes favor a local defendant. In a proceeding brought in Buffalo for the condemnation of cherries canned in the vicinity, the jury returned a verdict in favor of the claimant. In explanation of its verdict, the jury submitted to the judge the revealing statement which follows:

This jury after long deliberation further desires to state to this court that from the admitted facts in this case, which show that the management of the Westfield Canning Company in conduct and treatment of the cherries in question were either careless, incompetent, or wilfully negligent after knowing that the cherry season of 1924 was an abnormal

[63] See, *e.g.*, United States v. Boeckman, 176 Fed. 382 (C. C. N. Y. E. D., 1910), which followed *In re* Wilson, 168 Fed. 566 (C. C. D. R. I., 1909).

[64] For example, in construing the confectionery sub-section of §7, prohibiting the use of certain named substances "or other mineral substances," the doctrine of *ejusdem generis* was applied to restrict the meaning of "other mineral substances" to minerals used to increase bulk and weight at the expense of quality in French Silver Dragee Co. v. United States, 179 Fed. 824 (C. C. A. 2d, 1910), and was not so applied in United States v. Oriental Dragee Co., Not. Judg. 176 (D. N. J. 1909).

[65] The same product with the same label was held misbranded in United States v. Scanlon, 180 Fed. 485 (N. D. Ohio, 1908), and not misbranded in United States v. 68 Cases of Syrup, 172 Fed. 781 (E. D. Ill. 1909).

[66] United States v. Johnson, 221 U. S. 488 (1911).

[67] 37 Stat. 416 (1912), 21 U. S. C. A. §10.

[68] See F. B. Washburn & Co. v. United States, 224 Fed. 395 (C. C. A. 1st, 1915).

[69] See United States v. Coca Cola Co., 241 U. S. 265 (1916).

one, in not taking such special care and precautions that such conditions require, knowingly to market such goods which were far below the standards of other concerns shows gross carelessness and mismanagement.

This jury in consideration of the canning company's stock being held largely by the farmers and fruit growers of the community feels that they would be great sufferers if any adverse conditions affected the company. We, therefore, hope that the stockholders will demand a thorough investigation of the concern and see that this plant is as good and can produce as fine a quality of goods as any in the state and respect the pure food laws.[70]

The establishment of legislative standards in lieu of the administrative standards whose validity may be an issue in any trial would reduce the risk both of adverse interpretation and of misguided jury verdicts. The establishment of such standards has long been urged by the Administration. Once established as reasonable, such standards would no longer be open to question. Except in so far as the original Act incorporated the definitions and standards of the United States Pharmacopoeia and the National Formulary, it provided no legislative standards.[71] Congress has since enacted standards for apples[72] and butter.[73] The McNary-Mapes Amendment providing that any substandard canned food (except canned meats) shall be deemed misbranded unless it bears a label prescribed by the Secretary of Agriculture indicating that it is substandard,[76] represents, therefore, a departure from past practice.

The Secretary of Agriculture is authorized by this Amendment to promulgate standards for canned foods and to prescribe the labels that must be affixed to canned foods whose quality falls below the prescribed standard. In the discussions in Congress immediately preceding the passage of the original Act in 1906 it was specifically pointed out that the proposed statute neither provided for nor authorized any binding standards but that all enforcement was put in the hands of the courts.[75] It is very doubtful whether the Act would have passed at that time had the executive been given any great amount of power.[76] In the first case brought to test the validity

[70] (1925) 20 AM. FOOD J. 482, quoting from the Buffalo *Morning Express*, Aug. 3, 1925.

[71] The Act, as has been pointed out, did give to the three Secretaries a power to make rules and regulations which, if reasonable and within its terms, have the force and effect of law. See note 20, *supra*. These must be distinguished from the purely administrative standards and definitions promulgated by the Secretary of Agriculture. These have been declared to be determinations of fact upon which the law is made to depend and not law. United States v. Frank, 189 Fed. 195 (S. D. Ohio, 1911), quoting with approval a statement similar in tenor by Lurton, J., in Coopersville Coop. Creamery Co. v. Lemon, 163 Fed. 145, 147 (C. C. A. 6th, 1908).

[72] 37 STAT. 250 (1912), 21 U. S. C. A. §20.

[73] 42 Stat. 1500 (1923), 21 U. S. C. A. §6.

[74] 46 Stat. 1019 (1930), 21 U. S. C. A. §10.

[75] See 40 CONG. REC. 1923; 9495; 9735; 9740 (1906).

[76] During the consideration in the Senate of an urgent deficiency appropriation bill for the Department of Agriculture, Jan. 25, 1909, Senator Heyburn had the following to say:

"We absolutely refused, in enacting the pure-food law, to consider favorably the proposition of establishing standards by legislation. . . . It is the spirit of the pure-food bill that the courts should determine these questions [of adulteration and misbranding] and that no other definition than that of the courts should constitute a rule of action under the law; . . . It was the essence of that principle in the pure-food law that as much as anything else held it back in Congress for almost a quarter of a century. People would not submit to the principle that we should establish standards by legislation. The people who intelligently considered that measure demanded that each case should stand upon its own facts, and when the Senate expressed its final conclusions the law was so written." 43 CONG. REC. 1360 (1909).

of a standard established under the Amendment, the District Court for the Southern District of Indiana held the standard unconstitutional.[77] An appeal is pending.

IX

The penalties provided by the statute are not severe,[78] and their leniency has been a target for criticism.[79] The Administration itself complained of their inadequacy in the 1931 Report in which it was stated:

> Not infrequently firms are encountered which repeatedly violate the law, paying the fines imposed under this section whenever shipments are apprehended by the department and legal proceedings brought, but apparently regarding those penalties as in the nature of a license fee for doing an illegitimate business. While firms of this character do not persist in business indefinitely, a more positive deterrent effect would be insured if more severe financial penalties could be imposed. It is practically impossible to secure jail sentences, authorized in second offenses, where the shipper is a corporation.[80]

The quantity of goods seized is seldom such as to subject the manufacturer to serious loss. The dealer who may not be in a position to know the quality of the goods stocked by him can protect himself from criminal prosecution by securing a guaranty, provided for by Section 9 of the Act, from his seller, which shifts the risk of prosecution to the guarantor.

It is difficult to estimate the value of the publicity afforded prosecutions and seizures under the Act through the publication of notices of judgments. These are seldom noted by periodicals of general circulation, but trade journals tend to inform their readers of such actions. The liability to seizure of goods known to have been held in violation of the Act renders wholesalers and retailers chary of stocking them. Where the manufacturer has its own channels of distribution, this sanction is, of course, unavailing.

The fact that offending products may be seized simultaneously in various parts of the country has given rise to a problem of considerable difficulty. It has been held that the institution of multiple seizure proceedings in various parts of the country against the same product may be enjoined, on the theory that irreparable injury may be done to manufacturers of the product while the cases are being litigated.[81] In line with this decision is the holding of a Circuit Court of Appeals

[77] Morgan v. Nolan, 3 F. Supp. 143 (S. D. Ind. 1933).

[78] The penalty imposed by §2 for a first offense is a fine not exceeding $200; for each subsequent offense, a fine not exceeding $300 or imprisonment not exceeding one year or both, in the discretion of the court. Somewhat higher penalties are imposed by §1 for manufacture in the District of Columbia and in the territories. The average fine under both sections in successful prosecutions from Jan. 1, 1907 through June 30, 1931 was less than sixty-six dollars. There seem to have been only two jail sentences ever imposed. See Note (1932) 32 COL. L. REV. 721, 734 *et seq.*

[79] See KALLET & SCHLINK, "100,000,000 GUINEA PIGS" (1933) 213-219.

[80] REP. CH. F. & D. ADM. (1931) 4.

[81] National Remedy Co. v. Hyde, 50 F. (2d) 1066 (C. A. D. C., 1931). The court stated, p. 1068: "Inasmuch as every district attorney to whom the Department makes certification must institute appropriate proceedings, by indictment or libel for condemnation, or both, it is evident that, even though the findings of the Department are merely administrative, nevertheless, if such certification should be made to the district attorney in every district where a product might be found, the manufacturer would be

that where seizure proceedings brought against an article as misbranded under the Insecticide Act have resulted in judgment adverse to the Government, the Government will thereafter be estopped to institute similar proceedings against a different shipment. The court used the following language:

> If the government is not bound by an adverse judgment, neither is the appellant. Hence, without modifying its formula or changing its labels, it could, notwithstanding the decree herein, ship its preparation into other territory, and indeed into the same territory, with the hope of a more favorable result elsewhere, or next time should the government bring other libels. And, instead of "peace and repose of society," the result would be chaos and endless turmoil.[82]

Although this decision was reached under the Insecticide Act, the terms of that statute as to misbranding are similar to those of the Food and Drugs Act,[83] and it would seem that the principle of estoppel would apply as well under one law as the other. The result seems to be that the Government must prove each case of misbranding, so long as the judgments are favorable to it, while the first ruling for the defendant will automatically bar any further proceedings against an article so long as its formula and label remain the same.

Directly contrary to this case is the holding of a district court in a case which involved a subsequent seizure of a proprietary medicine under the Food and Drugs Act. The court decided that the prior decree for the defendant might be shown as conducing to an application of the doctrine of *stare decisis* but that it was not *res adjudicata*.[84] Since there is no Supreme Court ruling on the question, which of these two latter decisions will be followed is a matter of surmise.

It seems clear, however, that a single seizure proceeding will not be enjoined.[85] The validity of the seizure may be tested in the libel proceeding, and consequently the remedy at law is adequate. Where, however, the case involves the import of goods alleged to offend the Act, an injunction seems appropriate since the denial of entry is a matter for administrative discretion. Of course, relief will be granted only when such discretion is palpably abused.[86] The remedy of injunction would also

crippled or ruined long before the final adjudication in the court could be had. Such a result, we think, was not contemplated by Congress, except possibly in unusual cases where drastic action would be necessary for the immediate protection of the public. Is this a case of that character? We think not."

[82] Geo. H. Lee Co. v. United States, 41 F. (2d) 460-462 (C. C. A. 9th, 1930).

[83] Compare §8 of the Insecticide Act, 36 STAT. 331 (1910), with §8 of the Food and Drugs Act, 21 U. S. C. A. §10.

[84] United States v. Certain Bottles of Lee's Save the Baby, *supra* note 60.

[85] Shawnee Milling Co. v. Temple, 179 Fed. 517 (S. D. Iowa, 1910). The court said that injunction will lie to restrain the enforcement of a criminal or penal statute only when the statute is unconstitutional or otherwise invalid, and property rights are invaded in the attempt to enforce it or when often repeated attempts to enforce it create a multiplicity of actions. The court found that property rights were invaded, but held the statute constitutional as being a valid exercise of the federal power to regulate commerce. The question as to whether the product was adulterated under that statute was held to be for the jury.

[86] Ambruster v. Mellon, 41 F. (2d) 430, 432 (C. A. D. C., 1930). The court in this case refused to review the Administration's decision on the ground that the exercise of its authority had not been shown to have been "capriciously or arbitrarily" abused.

seem appropriate to restrain the establishment of legislative standards such as those contemplated by the McNary-Mapes Amendment.[87]

X

It is without the scope of this paper to consider the adequacy of the substantive provisions of the Act and the proposals which are current for its amendment. These are discussed elsewhere in this issue.[88] That amendatory legislation is needed is manifest. The Chief of the Administration has stated that the Food and Drugs Act is now enforced even more strictly than during Dr. Wiley's era,[89] yet it is a far cry from the following publicly-expressed and enthusiastic appraisal of the Act, in 1907:

> It is without exception the most complete, overwhelming and bloodless victory that legislation has ever accomplished. Whether the consciousness of guilt, the desire for reformation, the appreciation of anticipated benefits or fear of prosecution has produced this consequence, is an open question, but whichever motive has been the dominant one, the evils which induced the legislation have been already practically removed and while, of course, the future is bound to bring about some instances of statutory violation, yet, in the main, the purposes of the Act have been already realized,[90]

to the statement of the Chief in his report for 1932:

> Some . . . comments and inquiries reveal that a considerable portion of the public is perhaps expecting greater protection through the enforcement of the pure food and drug law than the legal authority conferred by that legislation will permit. . . . If the public is depending on the act for protection in instances where it has no protective provisions, it is worth while to inform consumers of the law's limitations so that they may not suffer through a false sense of security.[91]

[87] An injunction against such a standard was granted in Morgan v. Nolan, *supra* note 77.

[88] See Fisher, *The Proposed Food and Drugs Act: A Legal Critique, infra* p. 74; Burton, *What the Food Manufacturer Thinks of S. 1944, infra* p. 120; Kallet, *A Consumer Looks at the Food and Drugs Bill, infra,* p. 126.

[89] Hearings, *supra* note 38, at 343.

[90] Reed, *Some Aspects of the Federal Food and Drug Act,* ILL. STATE BAR. ASSN. (1907) 99, 102.

[91] REP. CH. F. & D. ADM. (1932) 11.

TECHNICAL PROBLEMS IN FOOD AND DRUG LAW ENFORCEMENT

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The profound changes in our economic system brought about in the past quarter century by technological developments in the industrial world have been attended by a striking evolution of the methods of manufacture and distribution of foods and drugs. Shifting sources of raw materials, introduction of new products and processes, increasing plant capacity for mass production, sharpening competition, consumer demand for more ready-to-serve foods, all have contributed to the swiftly changing picture. However real may be the social benefits of transferring the preparation of the bulk of our foods from the kitchen to the factory, the advantages have not been always unalloyed. While certain hazards like botulinus poisoning in canned foods have been practically eliminated by the carefully controlled time and temperature of cooking generally prevalent in commercial canneries, other hazards both to the health and pocketbook of the consumer arise from new technical methods and cut-throat competition. New substances of dubious physiological effect may find their way into foods, or well known poisons may be introduced by new processes. Guided by expert technical advice, sharp-shooting manufacturers resort to sophistications. New drugs, or old drugs in new combinations, may fall short of their reputed potency. It is in these fields that the regulatory technician finds his problems.

Lacking adequate funds for prompt correction of all illegal abuses as they arise in the vast field of food and drug production and distribution, regulatory organizations must adopt a system of projects under which the appropriation allotted to each commodity group is proportional to the importance of the violations occurring in the group as measured by their seriousness to consumers. This plan insures greatest attention to offenses against health. In proceeding against them some of the gravest technical difficulties are met.

It has been rightly said that the policy of the Federal Food and Drugs Act regarding added poisonous substances in food is an inverted one since the law places the obligation on the Government to show that the contaminated food may be harmful to health, rather than on the manufacturer to show that it will not. There is a wide range beween dosages of poisons which produce immediate and definitely identifiable

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harmful effects and the quantities which may, on prolonged use, cause a gradual undermining of health. While the Supreme Court has held that if a food, by reason of an added poisonous ingredient, may possibly injure the health of the strong or the weak, the old or the young, the well or the sick, it comes within the ban of the statute,[1] the toxicologist testifying in a court trial must nevertheless base his conclusions on tangible facts rather than on mere forebodings of harm. Where poisons in foods are found in minute quantities the proof of their harmfulness may present most serious difficulty. Complications arise from the fact that traces of poison continuously consumed may manifest results only after a period of years; first evidence of poisoning from infinitesimally small daily doses of lead have appeared as long as a decade or more after the beginning of the exposure. If the particular poison is a new chemical about which little is known, medical and pharmacological literature may afford no help. If it has been extensively investigated observations may have been confined to larger doses than occur in the food under consideration. Recourse must be had in many cases to protracted and expensive laboratory work on test animals, and here the picture is again clouded by the uncertainty of translating effects on animals into effects on man.

If the poison is one recently introduced in foods, methods for its quantitative determination may be lacking. Intensive research is then necessary to devise reliable methods from the results of which the toxicologist can draw his conclusions. These methods must be not only accurate, but must have the virtue of speed so that many samples can be examined and prompt results obtained by a limited laboratory personnel.

Certain fluorine compounds were introduced a few years ago as insecticides for fruits and vegetables. Pharmacological literature contained much evidence that some of these compounds are acutely poisonous in fairly large doses. But there was little information on the particular compounds used in the new insecticides, and none at all on the minute quantities that would be consumed as spray residue. Available chemical methods proved inadequate for determining such quantities. One break of luck came for the regulatory technicians when at about this time workers in the University of Arizona announced proof that mottling of human teeth, prevalent in certain areas of the state, was caused by traces of fluorine naturally present in the water supplies. Fluorine interfered with the deposition of lime in the teeth. Structural weakness as well as discoloration followed. These facts suggested other questions. How much fluorine would cause the damage? If it acted in this way on the teeth, might it not interfere also with the deposition of lime in the bones? Might it affect other parts of the body? By using various fluorine compounds in the diets of laboratory animals the Arizona workers and other scientists set out to find the answers. Regulatory chemists joined in the hunt for suitable quantitative methods. These have now been perfected and the pharmacological work has sufficiently

[1] United States v. Lexington Mill & Elevator Co., 232 U. S. 399 (1914).

progressed to permit tentative conclusions as to the quantity of fluorine which may be injurious. Undoubtedly it will be many years before the information on fluorine approaches in comprehensiveness that now available on such historic poisons as arsenic and lead.

While the most important function of the regulatory technician is to acquire facts on which the provisions of the law can be invoked for the protection of public health, he has also countless intriguing problems in the detection of violations which merely deplete the consumer's purchasing power, and incidentally enhance that of the manufacturer. Peculiarly enough, some of the strongest court interpretations of the law have arisen out of cases where the damage to the consumer was comparatively small and the food involved of minor importance. Such was the so-called "Vinegar Case," in which the United States Supreme Court held that the law forbids deception conveyed by indirection and ambiguity as well as by direct misstatement of fact.[2] Back of this litigation lay the solution of a technical problem typical of the simpler, garden variety. The case was based on a product labeled "Apple Cider Vinegar" made by soaking dried apples in water, expressing and fermenting the infusion. The cost of producing this vinegar was less than that of vinegar made from the juice of fresh apples. Laboratory methods had not been developed for detecting the substitution of the cheaper article; in fact, the conventional analytical procedure for vinegars failed to show any difference in the two products. The law does not authorize factory inspection, and it was unlikely that the manufacturer would permit inspectors to witness the manufacture of the vinegar and its subsequent delivery in interstate commerce. It was necessary, therefore, if effective regulatory action was to be taken, to develop methods whereby the two vinegars could be differentiated through objective examination of samples collected from interstate shipments. It was known that the dried apples used by the manufacturer had been bleached by the usual process of exposing them, while drying, to the fumes of burning sulphur; otherwise the finished vinegar would have been too dark in color. It seemed probable that the sulphur fumes absorbed in the dried apples would be carried into the finished vinegar as sulphates. A short investigation showed this was just what happened. While cider vinegar contains some sulphates, the dried apple product contains several times the normal quantity. Seizures were made on this evidence, but the manufacturer let them go by default while his chemist sought ways and means of eliminating the incriminating sulphur. An answer was quickly found in the addition of carefully calculated amounts of barium carbonate which combined with the excess sulphates to form one of the least soluble compounds known, barium sulphate. When this settled out, the vinegar had a normal sulphate content, and the regulatory chemist had to begin all over again. Some time was spent in investigating the volatile constituents of vinegar on the theory that in drying apples some change would occur in these which could be detected in the vinegar. But as so often happens in scientific research, results were negative or at least too uncertain for court use.

[2] United States v. 95 Barrels of Vinegar, 265 U. S. 438 (1924).

The attack shifted to an attempt to detect the infinitesimal quantity of barium sulphate that might still be in the vinegar, since no substance is known to be wholly insoluble. By concentrating a large quantity of the vinegar to about 1/200 part of its original volume, employing complex chemical means to get rid of the interfering substances normally present in vinegar, a minute quantity of a white precipitate could be filtered off. Was it barium sulphate? The spectroscope answered in the affirmative. No barium could be found in cider vinegar. This evidence, backed by the fact that the factory was receiving amounts of barium carbonate for which it could have no other use, was the ground for further seizures. Thus cornered, the manufacturer in defense of his lucrative business turned to court battle with the final result that the Supreme Court sustained the charges in its sweeping interpretation of the misbranding provisions of the Act.

Technological developments in mass production, desirable in themselves, sometimes present opportunities for abuse by unscrupulous manufacturers. The old fashioned housewife who put up her own jellies was usually worried about her results until the hot mixture of fruit juice and sugar actually jelled in the glasses. Only the most skillful manufacturers who knew how to buy fruits in just the proper stage of maturity undertook to put out a varied line of jellies other than the cheap apple-base type. Then commercial pectin was developed. This is the fruit substance which, with sugar and the acidity usually normal to fruit juice, causes jelly to jell. It is abundant in apples and in the rinds of citrus fruits. It can be produced cheaply from such by-products as apple pomace and citrus fruit peel. The pectin content of fruits decreases with maturity so that many fruits at the most luscious stage of ripeness will not make jelly without long flavor-destroying boiling, if at all. By adding a few tenths of a per cent of pectin they jell with a short cook. But a "jell" can be made from water, sugar, acid and pectin with no fruit juice whatever. Such a product has neither the appearance nor taste of jelly, but the manufacturer who wants to cut down on the expensive fruit juice ingredient can use half fruit juice and half water. The flavor and color are attenuated, but the product is not readily differentiated from the straight fruit juice article. A manufacturer so inclined can take advantage of the same property of pectin by substituting water for part of his fruit in jam and preserves. If he uses no pectin the fruit would be likely to separate to the top of the jar and thus advertise its deficiency, but with pectin to "set" the mass the fruit remains uniformly distributed and the deficiency is concealed.

When pectin became commercially available many manufacturers did not use it solely to improve their output. Methods to detect even gross deficiencies in the fruit content of jams and jellies had not been worked out. The technical difficulties were emphasized by the wide variation in the composition of fruit. The ancient saw, "Nature abhors a vacuum," has given way to the more truthful observation, "Nature abhors precision." In putting together the constituent parts of fruits she is acting the part. Composition varies with horticultural varieties, geographic location, weather

conditions, degree of maturity, and other factors. "Big Joe" strawberries grown in the Norfolk area during a rainy season differ from fruit of the same plants in a dry season and are likely to differ even more from the "Perfection" variety grown in the same place or in Tennessee or Oregon. This is also true of other preserving fruits. Hundreds of analyses failed to disclose the occurrence of any single constituent in sufficiently constant proportion to serve as an accurate index to the quantity of fruit in the finished jam or jelly. But a study of the mass of analytical data began to show that some of the ratios between two or more constituents are fairly constant. By working out several of these for each fruit, the chemist was able to determine with acceptable accuracy the fruit content of finished jams and jellies. Before this time-consuming work could be completed the preserving industry had been demoralized by the abuse of pectin, with the consumer acting the usual rôle of the innocent bystander. It took years of extensive regulatory proceedings by the Government, aided by the better element of the industry, to correct the situation.

Progress in scientific knowledge sometimes reveals unsuspected and unintentional abuses of public welfare, none the less damaging because unintentional. It may be that we are now faced with this situation in the growing practice of adding vitamin D to various infant foods. This vitamin in proper dosage is almost specific for the prevention and cure of infantile rickets, a disease all too common in northern latitudes where, because of their limited exposure to sunshine, babies may not obtain an adequate supply of their own vitamin D to supplement that contained in their diet. Cod liver oil and several other fish oils are rich sources of this vitamin, but it is also extensively produced artificially, notably by irradiating a substance called ergosterol with ultraviolet light. The potency of the manufactured product is determined by feeding it in measured quantities to a group of rats in which rickets has been artificially produced, and comparing its effects with those obtained by feeding a similar group with measured quantities of cod liver oil. Knowing the dosage of cod liver oil required for an infant, the manufacturer using irradiated ergosterol in his baby food has been adding an equivalent quantity of the rat-standardized product. In his labeling and advertising claims asserting the food is equal in vitamin D to a stated amount of cod liver oil, he has had the backing of vitamin experts generally; but recognized authorities have now reported results on feeding a vegetable oil solution of irradiated ergosterol, it is only about two-fifths to one-third as potent when fed to babies as when fed to rats. Will this discrepancy be found in baby foods containing irradiated ergosterol? Have we over-estimated the power of such foods to prevent or cure rickets in children? No one can say with certainty. The answer must be found by delving deeper in the field of nutrition than science has so far gone.

The regulatory technician has sometimes solved baffling problems only to suffer the disappointment of failure to get his facts across to juries of laymen in the trial of cases. Years ago the sanitary conditions in many tomato catsup plants were atrocious. Field-run tomatoes were put through without bothering to sort out rotten

fruit; utensils, tanks and pipe lines were unwashed and accumulated coatings of slimy, foul smelling material. Spices masked the undesirable flavors that might otherwise have been manifested in the finished product. No method was known whereby such filthy material could be detected by objective examination. It was known that spoilage is caused principally by two classes of microörganisms, molds, and yeast, but these may be on sound tomatoes and their mere presence in catsup is not proof of spoilage. Microscopists devised a method for counting the mold filaments and yeast cells in the catsup and found by making hundreds of tests that there is a definite relationship between these counts and the percentage of rotten material in the raw tomatoes or the degree of spoilage due to contamination and fermentation in the factory. Seizures were made of shipments of catsup which the microscope showed to have been prepared from thoroughly rotten stock. In the trial of one of the initial cases the defense counsel brought out the intricate technical details of the method and skilfully effected the confusion of the jury. Much was made of the point that from each of the several bottles in the sample only one or two drops of the catsup were actually examined. Should a whole carload of this splendid food product be destroyed on what an impractical scientist thought he saw in a few drops through a high powered microscope? Traditional American freedom must be preserved against the encroachments of mendaciously meddling bureaucracy. The jury found for the claimant, and the catsup was released, perhaps to be consumed on the tables of some of those who rendered the verdict. But this decision did not impair the inherent value of the method. It was soon recognized and adopted generally by food technicians. A similar attack on the method today would probably fail because of the supporting testimony that would be available from technicians in the industry itself. And through the years since the method was devised it has brought revolutionary improvements in the sanitary conditions of catsup factories.

Perhaps the most difficult scientific testimony to present to a lay jury is that required for the successful prosecution of fake medicines. Many laymen believe in the curative effects of drugs with far greater conviction than they hold for their views in other fields of science. They had influenza; the doctor administered aspirin; they recovered. Aspirin is therefore a remedy for influenza. They have no notion of the prevailing medical opinion that the sole function of aspirin is to lessen somewhat the malaise of the patient; that it exerts no effect on the progress of the infection which causes the disease. There is a will to believe in the therapeutic efficacy of drugs that baffles understanding until we are reminded that recovery from disease is spontaneous in about four-fifths of the cases and occurs irrespective of the use of medicaments. This passion for belief in miracles from pill boxes was recognized by Judge Geiger in the following words from his charge to the jury in a case against a nostrum bearing flamboyant therapeutic claims:

> Now, in that connection you should examine this language in the light of the purpose of this law, which is to protect humankind against the consequences of human weakness, or human frailty, of human credulity or the disposition to believe, or of human gullibility.

You should examine it in the light of the disposition of the ordinary humankind to wish to believe in the potency of remedial agents to relieve them from ills from which they are actually or conceivably suffering.[3]

This attitude by lay jurors toward the healing power of drugs handicaps the effective presentation of medical testimony and contributes materially to the difficulty already inherent in patent medicine cases, that of proving fraud. Involving as it does the establishment of what the nostrum maker actually thinks of his product as compared with what he says about it, this difficulty is sometimes a staggering one. Technically trained inspectors ferret out the required evidence of bad faith. Perhaps local physicians have told the manufacturer his medicine is worthless. Dissatisfied customers may have reported to him their sad experiences. He may have continued the publication of testimonials after he knew the writers were dead from the disease supposed to have been cured. He himself may have had the disease and, not relying on his own concoction, sought the attention of physicians. In countless ways his duplicity is revealed. Unearthing these facts requires ingenuity and persistence of as high order as the solution of a knotty laboratory problem.

The analyst's job of unscrambling some patent medicines, so the physician can evaluate their therapeutic worth makes the most intricate jig-saw puzzle look simple. The manufacturer who offers to treat your self-diagnosed distemper has literally thousands of materials he can choose from to make an infinite number of combinations exasperatingly difficult to unravel. Included in these may be such weird Chinese medicaments as powdered bedbugs and deer-horn, or Voodoo decoctions of nondescript herbs, as well as conventional drugs like quinine or Epsom salts. Some of the herb medicines may be composed of extractives from a number of plants, none of which contains characterizing constituents for which identification tests are known. The successful merchandizing of many preparations depends upon the fabrication of a background of some great scientific discovery unknown as yet to chemists and doctors. Experience has shown that in prosecuting such cases the defense is apt to center on a claim for some mysteriously potent substance the analyst has been unable to find; that this substance was the discovery of the late Dr. Hokum, renowned specialist, who, inspired by his pity for stricken humanity, labored a lifetime to develop this matchless boon to health and happiness. Only by the most thorough and painstaking investigations can analysts and inspectors prepare themselves to meet this counter-attack.

The formulation of food standards to aid in the control of so-called economic adulterations often requires laborious amassing of technical data. The recently announced standard for moisture in dried apricots will serve to illustrate. This commodity is made by evaporating moisture from ripe apricots, but it is neither desirable nor practicable to remove all the moisture. At what point in moisture content does the article become a dried apricot? Too much moisture is conducive to spoilage but what is more important is that the consumer is required to pay for it at dried

[3] Reported in Notice of Judgment 5906, U. S. DEPT. AGR. S. R. A,. Chem. Supp. 49, at 510.

fruit prices. If the product contains too little moisture it is hard, unattractive, and undesirable. Investigation showed a general agreement among consumers that they expect the fruit to contain enough moisture to give it pliability and other desirable characteristics but no more. Just what that meant in terms of percentage of moisture was a question which could be answered only by determining moisture content and physical condition of hundreds of samples, keeping in mind always the possible influence of varietal, geographical, and seasonal factors. The standard for moisture thus set does not in itself have the effect of law since the food and drugs act does not authorize administrative establishment of legally binding standards except in the limited field of canned foods. But the data obtained by the investigation will be useful in sustaining cases in which it will be alleged, not that the fruit differs from the standard, but that it contains excessive moisture and is not entitled to be sold as dried apricots.

The regulatory technician in the food and drug field is unlikely to find himself without the challenge of problems sufficiently interesting and inspiring to bring forth the best he can give. He may be favored by neither fame nor substantial remuneration but he has whatever satisfaction may be derived from the knowledge that solution of his problems is a tangible contribution to social welfare.

SOME ECONOMIC CONSEQUENCES OF COMMODITY CONTROL

CARL L. ALSBERG*

In appraising legislation intended to protect public health or prevent fraud, it is not enough to inquire whether the abuses aimed at are likely to be cured; political, economic, and social consequences need to be envisaged also. Only with due consideration of these should one venture to answer the question: Are the net consequences worth while? Clear thinking upon this question will probably become increasingly important, since control over commodities is likely to be extended merely to prevent fraud, even though no danger to the public health is involved. The purpose of this paper is to set forth a few of the factors that need to be kept in mind in answering the above question; limitations of space forbid exhaustive analysis.

Commodity-control legislation may handicap some of those who produce for export, if it causes higher production costs than in competing countries; but it may aid others by inspiring confidence in foreign countries in the quality of goods produced under control. Thus our Meat Inspection Act of 1906[1] leads to the sale of some lard as white grease and consequently to higher costs, and this in turn to change in the price relationships of lard and white grease throughout the world. Hog prices are affected thereby and, indirectly, the prices of corn and of such lard substitutes as vegetable shortening, margarine, and cottonseed oil. On the other hand, the Meat Inspection Act aids exporters because it inspires confidence in American animal foods. Indeed, a law providing for the inspection of meats for export was enacted some years before the Meat Inspection Act, not so much in response to an insistent demand for protection of the public as to conserve our export trade, jeopardized by the food laws of foreign countries. If the United States was to retain its foreign markets, it was necessary to clean house at home.

Many American manufacturers of that day regarded European food laws as really camouflaged embargoes or tariffs. The Meat Inspection Act, the Food and Drugs Act (also passed in 1906),[2] and the Plant Quarantine Act[3] have turned the tables on

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[1] 34 STAT. 674, 21 U. S. C. A., §§71-95.

[2] 34 STAT. 768, 21 U. S. C. A., §§1-15.

[3] 37 STAT. 316 (1912), 7 U. S. C. A., §§151-165.

them, and foreigners now make the same charge against the United States. Obviously, commodity-control laws contain the germ of not a little potential friction between nations; but they may also accentuate economic conflict at home—set the city against the country, the south against the north, the west against the east. Thus oleomargarine legislation has always been supported by the dairy farmers of the north and opposed by labor and also by the cotton farmers of the south who find an important outlet for cottonseed oil in margarine. Before the War, the food law sharpened the conflict between the grape growers of the east and those of California. Wine can be made from California grape juice without dilution, but in the east addition of water and sugar to the must may be necessary in bad years, if the wine is to be palatable. Because a ton of grapes then yields more wine, Californian vineyardists asked that food officials suppress the practice; an essentially economic sectional struggle became a matter for governmental intervention. Cases of this kind might easily be multiplied.

A different kind of conflict inevitably arises if control is based on the interstate-commerce clause of the Constitution, because some zoning of markets results, which may give rise to considerable intersectional political friction. Meat packing is zoned in this way because the channels of interstate and foreign commerce are closed to establishments without federal inspection. Only plants of some size are federally inspected. Further zoning results from the existence of municipal inspection. Meat products may not everywhere move freely from the country districts into a city or from one city to another or out of the state into other states or into export. Those who are advantaged endeavor through political pressure to exploit the system as a sort of internal embargo. The smaller packers doing a local business unhampered by federal inspection may enjoy appreciable advantages over their larger federally-inspected competitors. They may purchase animals at a low price that would not pass federal inspection. Their capital investment may be small because they need not meet the requirements of the federal government in regard to sanitation and the like. In his local territory, the local butcher is, therefore, often able to compete successfully with the great packer. On the other hand, because he is limited to the local market, he may sometimes have to divert certain kinds of edible material to low-priced non-food uses. The local consumer buys his meats at lower prices, but runs some risk of consuming meats from possibly-diseased animals. The local farmer gets a somewhat higher price for animals that might not pass federal inspection, and perhaps a somewhat higher price for those that would. There is less freighting of livestock and slaughterhouse products around the country. Centralization of the meat-packing industry tends to be prevented. Many small butchers continue to employ local labor, to pay local taxes, and to furnish a local market for livestock, but there are social wastes arising from the inability of small butchers to utilize by-products efficiently.

The Food and Drugs Act has not had as extensive zoning effects as the Meat Inspection Act, except upon the trade in market milk. The milk supply of a great

city like New York has to come from a great distance. Market milk has been delivered on occasion to New York from as far away as Wisconsin, where the costs of milk production are lower than in New York State. The regulations for New York and other cities involve very definite requirements in regard to sanitation on the farm, and they are enforced by municipal inspection. No dairyman whose plant does not meet these requirements is permitted to send milk into New York City. Obviously, it is difficult for a dairyman in the middlewest to have his farm inspected in order that he may ship to New York. The New York milk regulations, therefore act like a tariff or embargo and result in zoning the dairy business. A dairy farmer wishing to sell milk in several different states may have to meet the requirements of several cities; and these may not be consistent with one another. There have been times when a New Jersey farmer, wishing to sell milk in Philadelphia, Newark, and New York, had to submit to three separate and distinct inspections. The economic effects upon the milk consumer, upon the dairyman, upon the distribution of dairying over the United States, and upon the freight business of the railroads are obvious. Charges have not been wanting that milk inspection has been so shaped as to serve the ends of a tariff between the states.

Food manufacturers in large cities have sometimes produced goods which are permitted to be sold within the city that could not be sold in interstate commerce. For example, in the city of New York, ice cream has at times been produced and sold which could not be drayed to Hoboken or Jersey City without violating the federal food law. A confectioner who sold a 15-ounce box of candy in his home city has been known to truck candy in bulk to a branch house across a state line and there to pack in 15-ounce boxes, thus avoiding the necessity of complying with the net-weight provision of the federal food law and informing purchasers that his boxes did not contain a full pound of candy. The writer has known of cases in which food manufacturers have produced goods that were adulterated under the federal law or of very low quality to sell in their own city or state and a quite different, superior line for sale outside their state. There have also been instances in which local requirements were allegedly superior to the federal requirements, as, for example, formerly in New York City where skim milk could not be sold legally, whereas it could be shipped legally in interstate commerce if not misrepresented. The law may thus confer a competitive advantage on the small concern which need not comply with the federal law, because it does not do an interstate business. It has happened, though rarely, that such a concern, as it grew, found it advantageous to evade the federal law by establishing a branch factory in another state rather than to enlarge its existing capacity and ship in interstate commerce.

Obviously, commodity-control legislation may present all the economic effects of tariffs. While tariffs were low, the Meat Inspection Act restricted the importation of fresh, chilled, and frozen meat. Prices of meats in all importing and exporting countries unquestionably were, and perhaps still are, influenced thereby. To size up all

the consequences, it would be necessary to evaluate the losses to producers and gains to consumers in all foreign countries, as well as the benefits to American producers. It would be necessary also to balance the losses from higher prices to American consumers against the quite imponderable, though very real value of protection against meats prepared possibly under insanitary conditions. Perhaps the disadvantages to producers outside the United States are greater than the gains to the United States. Foreigners might be led to retaliate, and perhaps do, by buying less in the United States. This must ultimately follow in any event, because the foreigner can buy in the long run only if he is permitted to offer something in exchange. Foreign governments, even, may retaliate by tariffs, quotas, embargoes, and other restrictive measures aimed at American goods. In the United States, all producers for export are affected in proportion. Moreover, ill will may be generated with appreciable repercussions not merely upon American export trade but also upon tourist travel. In the case of the Meat Inspection Act, one can justify restriction of imports on the ground of public-health protection. In the case of other commodities not affected with a public-health interest, justification is sometimes more difficult.

The Tea Importation Act of 1897[4] is a case in point. It contains among other provisions a prohibition of the importation of tea below a certain quality.[5] The effect has been to limit importations from countries producing the lowest grades, and to weaken to some extent the power of these countries to buy from the United States. Importation from other countries has been favored and their capacity to buy American goods increased. The geographical distribution of tea culture has possibly been changed and price differentials between low and high grades widened. Since only the better grades are permitted entry into the United States, the average American price has probably been higher than it would otherwise have been. Per capita consumption in the United States may have been raised because no tea has been admitted so poor as to disgust users with tea drinking, but at the same time high prices may have restricted the market. Some of the very poor may have purchased less than otherwise they would have elected to buy. There may be consumer classes who prefer low quality at a low price to higher quality at a higher price because they are undiscriminating. On the other hand, those who are able to pay for average, or better than average, grades have had no very poor teas palmed off on them. Such considerations as these raise the question whether the best interests of consumers as a whole might not have been served better by a law which, in addition to preventing the adulteration which the present law prohibits, compelled adequate truthful branding instead of forbidding importation of low-grade teas.

Most people are apt to assume that the purpose of commodity legislation is to ensure them goods of high quality. However, a law accomplishing more than to ensure the consumer his money's worth is of questionable value. Quality is a relative, often a purely subjective, concept, for scarcity and esthetic considerations often de-

[4] 29 STAT. 604, 21 U. S. C. A., §§41-50.

[5] Such teas are admittedly neither more nor less wholesome than the better grades.

termine it. High quality has to be paid for. The cost of living would be raised enormously, if there were none but high-quality goods on the market. Indeed, in many commodity classes, there might not be enough to go around—canned peaches, for example, in which the difference between the very highest grade and the grades immediately below is not one of good value or flavor, but of appearance merely. It must be remembered that most of us buy with our eyes.

The cost of doing business may rise, even for the honest man, because of control legislation. Special forms of labeling and packaging may be required, or the keeping of books in a definite way, or manufacturing may have to be done under specified sanitary conditions, or chemists and other technologists may have to be employed, etc., etc. It is of no moment to business men if costs go up alike for all of them, since added costs are usually passed on to the consumer. Unfortunately, these costs are apt to weigh more heavily upon the small than upon the large business, for more capital may be required which the large concern can usually secure more easily than the small one. For a small business, the employment of technologists and the maintenance of testing laboratories may prove difficult, because it may increase fixed charges more than the volume of business permits. On the other hand, many manufacturers would be saved the cost of testing deliveries in the laboratory. The expenditure in labor and materials that would be unnecessary for this purpose, if falsification were punishable, it is impossible to estimate, but it would probably be very large indeed. Not the least gain would be social, for a vast improvement of business morals would result with repercussions on society as a whole that no one could appraise. The business man is often compelled to adulterate or be ruined. It may be true that honesty is the best policy in the long run, but many a manufacturer has not the resources to last for even a not-very-long long run. The effects of this kind of unfair competition on business ethics and upon the tone of the commercial world are undoubtedly profound and evil.

It is a fallacy to argue that, when the debasement of a commodity has become general, it is never of import to the public welfare, since demand and supply determine the price. Weighting of sole leather, for example, adds nothing to its wearing quality; it may give a false appearance and feel of firmness to inferior leather. Since it takes as much labor and nearly as much capital to produce shoes with inferior weighted soles as with superior ones, more capital and more labor are needed to keep a person in footgear for a given time if he wears inferior shoes than if he wears better ones. As an individual he may not be disadvantaged, if he has paid a low price for the inferior shoes that soon wear out, but there is social waste of capital and labor nevertheless, to say nothing of the waste of loading material (glucose and epsom salts) and the unnecessary manufacturing expense of weighting. In general, if costs of raw materials are small as compared with costs of labor and distribution, the production of low-grade goods is not in the national interest. On the other hand, if the low-quality goods are also serviceable and cheap, they become attainable for

larger classes whose standard of living may in consequence rise. The increase in demand may then make mass production possible, which in turn may more than wipe out the wastes of labor and capital resulting from the manufacture of the poorer product. The net result may well mean material social gains.

With increasing mechanization of industry, this has been the course of events in the modern world and especially in America. Labor is tending more and more to represent a smaller and smaller element in the costs of production. In consequence, cheap goods with a short life become better buys, especially goods subject to changes in style. The extreme case is the wood-pulp plate used for a single picnic meal, or the paper towel which, though used only once, is economical because the costs of laundering are saved. Such goods are typical of American economic life, and with them the tremendous development of junking in the United States. In the old world, goods are still expected to last, if possible, forever. Obviously, one cannot generalize about commodities as a whole. Each class of commodities has to be considered as a special case. Thus the question is more important for durable than for non-durable goods. General lowering of quality in merchandize, though accompanied by a lowering in price, is a matter of public concern as a question of national policy. It may well be that some check in the way of commodity-control legislation is in the public interest.

Social gains of this sort involve more or less change in manufacturing processes, but government control tends inevitably to crystallize and fossilize trade practices. The manufacturer, in considering whether or not it is wise for him to take up the production of a new product, especially if it is a substitute or imitation, must base his decision not merely upon his judgment of the probability of earning profits but also upon the probable attitude of law-enforcing officials regarding branding and other conditions of marketing. The protection of the public from frauds of necessity entails some discouragement of the introduction of new products, even though they be meritorious, and also some delay in the application of science and invention to industry.

It must be clear to the reader by this time that far-reaching political, economic, and social consequences may follow in the wake of commodity-control legislation, and that benefits cannot be weighed against disadvantages in any scientific manner, since neither the benefits nor the advantages can be measured in terms of social welfare. Each type and class of commodity presents its own problems. Each person must weigh benefits and disadvantages on the scale of his own social and political philosophy. There is probably only one point of view on which all would agree: it is that the public health must be protected, even at very high cost. To attempt to balance benefits to public health against economic or other social costs is to compare incommensurables. All that can be done is to recognize the existence of these costs and to reduce them to whatever extent is compatible with public health. When health is not involved, the striking of a balance in rather general terms is not impossible. It is in this unsatisfactory state that we must leave our subject.

THE AMERICAN MEDICAL ASSOCIATION'S WORK FOR CONSUMER PROTECTION

MORRIS FISHBEIN*

An intelligent and enlightened consumer is a safe consumer. The whole purpose of the work of the various councils and committees of the American Medical Association is not persecution or prosecution of the promoter and the quack, but education of the public as to what is sound in the field of medicine.

The first of the councils of the American Medical Association was the Council on Pharmacy and Chemistry. It was established primarily to advise the editor of *The Journal* relative to advertisements for proprietary medicines submitted to *The Journal,* with a view to limiting such advertising to products of known composition and established merit. As a result of this work, it became necessary to establish a laboratory to investigate the products so as to check the composition claimed by manufacturers. As the work grew, it became possible to publish each year a book called "New and Nonofficial Remedies," describing the products that had been accepted by the Council and which were therefore considered suitable for advertising in the publications of the Association.

Since, however, the Council on Pharmacy and Chemistry dealt only with ethical proprietary preparations sold to the medical profession the Bureau of Investigation was established to consider the claims made for nostrums and patent medicines sold to the public, and the laboratory of the American Medical Association was used to ascertain the composition of secret remedies, so that the claims made for them might be considered in relationship to their composition.

As this work of the Association developed, new councils and bureaus were gradually established. The Council on Medical Education and Hospitals has begun to be a rating agency for medical colleges and for hospitals, and also for laboratories which supply diagnostic tests and for roentgen-ray laboratories.

The Council on Physical Therapy was established to consider devices in the field of physical therapeutics, such as ultraviolet, diathermy, and hydrotherapy apparatus.

Finally when it became apparent that increasingly foods were being prescribed in the practice of medicine, when it became obvious that the new discoveries con-

* B.Sc., University of Chicago, 1910; M.D., Rush Medical College of the University of Chicago, 1912. Editor, *Journal of the American Medical Association, Hygeia.* Contributor to numerous periodicals; author of *Handbook of Therapy* (with Oliver T. Osborne) (1915); *Medical Follies,* (1925); *Doctors and Specialists* (1930), and many other works.

cerning mineral salts and vitamins would be exploited to the public by manufacturers who would not hesitate to exaggerate the qualities of their wares in order to increase their sales, the Committee on Foods was established to do a similar work in this field.

Unquestionably this philanthropic work on the part of the American Medical Association has meant vast savings in health and life, and a saving of money to the American people. Much of the work of the Consumers' Research and similar organizations is based on this pioneer work by the American Medical Association. It should again be emphasized that no manufacturer is permitted to pay one cent in relationship to the examination of his product and that no member of the public is ever charged for the information that is supplied. The money necessary to carry on this work is made by the publications of the American Medical Association, including principally *The Journal of the American Medical Association.*

Moreover, from the first, the work of these councils and bureaus has been given adequate support through the publicity department of the American Medical Association, through all of its periodicals, and through the absolutely consistent refusal to accept the advertising of any products that could not meet the standards of the various committees and councils.

It must be realized that the Food and Drugs Act protects the consumer so far as the package of the product is concerned, but bears no relationship to advertising separate from the package. This arrangement has made necessary the work of these councils. It is conceivable that the passage of new food and drugs legislation like that now proposed, which plans to control claims made in advertising as well as claims made on the package, will give the consumer the protection needed.

THE WORK OF THE BUREAU OF INVESTIGATION

ARTHUR J. CRAMP*

The Bureau of Investigation of the American Medical Association is an outgrowth or by-product of the Council on Pharmacy and Chemistry, although the Bureau has no connection with the Council. The Council on Pharmacy and Chemistry was brought into being in 1905 for the purpose of subjecting to scientific scrutiny the innumerable proprietary medicines that were offered to the medical profession for prescription purposes and passing on to the profession the results of such investigations. As the medical profession awoke to the way in which it had been deceived and humbugged by the exploiters of unscientific proprietaries, they began also to take an interest in those crude proprietary medicines known colloquially but incorrectly as "patent medicines"—that is, package medicines, usually of secret composition, sold to the public for the self-treatment of self-diagnosed ailments. Repeated and insistent requests for information coming first from physicians and later from the

* M.D., 1906, Wisconsin College of Physicians and Surgeons. Director of Bureau of Investigation, American Medical Association. Author of *Nostrums and Quackery* (1921).

public brought into existence the activity of the American Medical Association that is now known as the Bureau of Investigation.

Twenty-five years ago it was a rare thing for the Bureau to receive an inquiry from a layman. Today letters from laymen run into thousands annually. During the past few years the authors of certain school and college text-books on such subjects as General Science, Civic Science, Biology, Hygiene, etc., have incorporated in their publications material dealing with the nostrum evil and quackery as one of the health phases of community life. Some of these text-books urge the student to write to the Bureau of Investigation for information and to obtain supplementary reading and study the books and pamphlets prepared and issued by the Bureau. Each letter received is answered and, whenever possible, informative material sent to its writer.

In addition to receiving letters from individual laymen asking for information about specific nostrums or quacks, and from college and high school students seeking data for use in their classes, there is another phase of the Bureau's work that one hears little about, but which is having a far-reaching influence. For years those interested in truthful advertising have kept in close touch with the Bureau of Investigation and have sought from it information that could be obtained from no other source. The National Better Business Bureau and affiliated local Better Business Bureaus have been in close coöperation with the Bureau of Investigation since its inception. Many advertising managers of newspapers and magazines seek information from the Bureau of Investigation in an attempt to keep the advertising pages of their publications as free as possible from objectionable medical "copy." Requests for information from such sources come in daily. The influence that the Bureau of Investigation is exerting in this way will never be generally known and is appreciated only by those who are thoroughly familiar with its daily work.

Another class from which the Bureau receives many inquiries is laymen who have written municipal, state, or federal officials for information that they assumed these officials could furnish. Instance: Some widely-advertised fake is exploited, we shall say, from Chicago. A layman reading an advertisement wishes to make some investigation before parting with his money, and he writes to the Department of Health of the City of Chicago. That department notifies him that it is not in a position to answer his inquiry and refers the letter to the Bureau of Investigation of the American Medical Association, which sends the information requested, if it has such information—and it usually has.

Again: A group of quacks is operating in a certain state and a resident of that state, impressed with the plausibility of the advertising but still skeptical, writes to his State Board of Health for information regarding the quacks. The board replies that it has no information regarding these people and suggests that the correspondent write to the Bureau of Investigation of the American Medical Association. Or: A "patent medicine" swindle, national in scope, interests a layman who writes to the federal authorities at Washington for information about it. He is told

that they cannot give him any information but that the American Medical Association has a department that investigates questions of this sort, and it is suggested that he write to the Bureau of Investigation.

Then there are letters that come directly to the Bureau of Investigation from municipal, state and federal officials themselves seeking information on products or individuals coming within the scope of the department's activities. Conversely, the Bureau plays an important part in bringing to the attention of state and federal officials schemes and methods that seem to be a menace to the public health, a violation of the law, or both.

The Director of the Bureau prepares articles on "patent medicines," quacks, medical fads and fakes and other phases of pseudo-medicine, and these are published weekly in *The Journal of the American Medical Association*. The material is reprinted in inexpensive pamphlet form, each pamphlet dealing with a group, such as "Consumption Cures," "Cancer Cures," "Epilepsy Cures," "Cosmetics," etc. More than two million pamphlets have gone out to the general public and the medical profession. Later the same material is incorporated in the book "Nostrums and Quackery," of which two volumes have been issued. The first volume had two editions, the first edition appearing in the latter months of 1911 and the second edition coming off the press in December, 1912. The second volume was issued in the latter part of 1921. It is a book of some 800 pages, containing none of the material that appears in the first volume, but having a comprehensive cumulative index giving references to articles in both volumes. It is not too much to say that Volumes I and II of "Nostrums and Quackery" together comprise a veritable encyclopedia on the nostrum evil and quackery.

In addition to the books and pamphlets, a number of educational posters, dealing with various phases of the nostrum evil and quackery, have also been prepared. The first of these were prepared at the time that the Bureau had an exhibit at the International Congress on Hygiene and Demography in 1912. Health officials, recognizing their educational value, immediately began making requests for copies. As a result of this demand, many additional posters have been prepared, covering practically every phase of "patent medicine" exploitation and quackery. They are being used today at health exhibits, county fairs, state fairs, health expositions, "health weeks," and are also used in schools and colleges.

Supplementing the posters, there are a number of stereopticon slides, originally prepared for the use of the Director of the Bureau in giving illustrated talks on quacks and nostrums. A demand for such slides on the part of physicians, health officials and others interested in the public health resulted in a collection of slides being made, so arranged that they themselves tell the entire story ("legend slides" being interpolated between "illustrative slides") or, without the use of the "legend slides," for lecture purposes. These slides are available either for rental or purchase at or below cost. In addition, the Director of the Bureau gives a limited number of

illustrated talks on the "patent medicine" problem and on those cosmetics whose use may involve some health hazard.

The Bureau collects its information through (a) original investigations often supplemented by analytical work done in the Chemical Laboratory of the American Medical Association or in other high-class laboratories; (b) data received from federal sources (the Food and Drug Administration of the United States Department of Agriculture, post-office fraud orders, Federal Trade Commission, etc.) as well as from state and municipal boards of health; (c) information published in technical and other journals, both domestic and foreign and (d) reports of special commissions, etc.

In brief, the Bureau of Investigation is a clearing house for information on the nostrum evil, quackery and allied subjects. It is doing a work that is done by practically no other agency, a work that theoretically belongs to the state, using the word "state" in its broadest sense. Unfortunately, the exigencies of politics make it well-nigh impossible for health agencies to tell unpleasant truths when these involve huge vested interests. Nevertheless, if the public's health is to be served, these truths must be told. The medical profession of America, recognizing this fact, has assumed this responsibility and is discharging it through the Bureau of Investigation.

Naturally, the work of the Bureau arouses widespread opposition on the part of certain proprietary medicine interests and of quacks and charlatans whose methods may be dealt with in the Bureau's articles. Such opposition not infrequently expresses itself in libel suits. Many such suits have been brought against the American Medical Association, demanding amounts that total many millions. In the more than twenty-five years of the Association's work, both through its Council on Pharmacy and Chemistry and its Bureau of Investigation, only two of the many suits that have been brought against the Association have come to trial. In one—that involving a large "patent medicine" concern in a southern state—the suit resulted in what has sometimes been called a contemptuous verdict in favor of the plaintiff. The American Medical Association was assessed one cent damages and the plaintiff had to pay his own costs. In the other case, that of an individual exploiting an alleged cure for cancer who sued the Association because he had been called a quack, the jury decided that the American Medical Association was quite justified in its characterization.[1]

[1] Both these cases were tried in the federal courts, the first in Chicago and the second at Davenport, Iowa.

THE WORK OF THE COMMITTEE ON FOODS

RAYMOND HERTWIG*

The Committee on Foods is one of several public welfare and health departments of the American Medical Association. The Committee was created four years ago to pass on foods and food advertising in the interest of the public. It is delegated to use the influence of the Association for the merchandizing of wholesome foods and for the establishment of truthful advertising in their promotion. The Committee represents a social force operating in the field of foods; it is independent of commercial or political interests and receives no remuneration for its services. No charges are made for considering or accepting foods.

The Committee personnel (as of 1933) follows:

Morris Fishbein, M.D., Editor of The Journal of the American Medical Association, Chicago, Chairman.
Lafayette B. Mendel, Ph.D., Sc.D., Professor of Physiological Chemistry, Yale University, New Haven, Conn., Vice Chairman.
E. M. Bailey, Ph.D., Chemist in Charge, Analytical Laboratory, Connecticut Agricultural Experiment Station, New Haven, Conn.
Julius H. Hess, M.D., Professor of Pediatrics, University of Illinois School of Medicine, Chicago.
Philip C. Jeans, M.D., Professor of Pediatrics, University of Iowa School of Medicine, Iowa City.
Edwin O. Jordan, Ph.D., Sc.D., Professor of Bacteriology, University of Chicago.
James S. McLester, M.D., Professor of Medicine, University of Alabama, Birmingham, Alabama.
Grover F. Powers, M.D., Professor of Pediatrics, Yale University, New Haven, Conn.
Mary Swartz Rose, Ph.D., Professor of Nutrition, Teachers College, Columbia University, New York City.
Russell M. Wilder, Ph.D., M.D., Professor of Medicine, Mayo Foundation, Mayo Clinic, Rochester, Minn.
Raymond Hertwig, B.S., Secretary of the Committee, American Medical Association, 535 North Dearborn Street, Chicago.

The Committee grants the privilege for display of its "Seal of Acceptance" with foods presented for consideration which fulfill the requirements of its rules, regulations, and decisions. The seal may be displayed on the container label or in any advertising related to accepted products. Its use is subject to the restrictions of the rules of the Committee. All foods with but few exceptions, such as retailed liquid milk and ice cream, are eligible for acceptance. The exceptions are products which quickly spoil and are especially subject to contamination that may cause disease. The seal on containers of such foods may give a false assurance of safety. Advertising independent of a food itself for all classes of foods, however, will be considered.

* B.S., Secretary, Committee on Foods, American Medical Association. For eleven years with the Bureau of Chemistry of the U. S. Dept. of Agriculture. Author of scientific publications on food methods and food composition.

The Committee requires that accepted foods, either dried, concentrated, or in any manner processed, packed, or canned, shall retain their natural nutritional values in highest degree possible by most efficient methods of preparation available to the trade. They shall be wholesome and shall meet all food law requirements. The claims shall accord with the physical and chemical composition of the foods, their biological or nutritional values, process of manufacture, sterility, freedom from pathogenic organisms, mode of preservation, keeping qualities, quality of excellence, source, and raw material from which made.

The Rules and Regulations of the Committee in pamphlet form are distributed free to food manufacturers, advertising agencies, and others on request. The Rules define the purpose of the Committee, its scope and policy, the significance of the seal; outline the requirements governing the use of the seal, the submission of new advertising and labels subsequent to acceptance, rules governing package labels and advertising directed to the public and to physicians; and include an outline of the form of submission of foods for consideration by the Committee. The Rules are amended from time to time to meet the requirements of the work as it develops. An important recent amendment calls for the automatic submission of proof of all new advertising of accepted foods at the time of preparation. This requirement assures that the Committee will be familiar with all advertising for accepted foods and thereby better prevent any improper advertising militating to discredit the seal. Although this requirement may work some inconvenience on manufacturers and advertising agencies, it is a necessary step as inappropriate claims have been found to creep unwittingly into advertising for accepted foods in spite of conscientious effort by the sponsors to comply with the requirements of the Committee.

The Rules governing the package label and advertising state the policies of the Committee on food package labels and distinguish between food advertising to the public and to physicians. Foods with fanciful brand names shall be accompanied by statements describing the nature of the food or the identity of the ingredients. This requirement is vital for preventing misleading claims. Names of diseases shall not be used in advertising to the public. Statements regarding nutritional disorders arising from inadequacy of the diet in nutritional essentials are permissible. Advertising to physicians may discuss the use of foods in the diet of the sick, but statements tending to transform foods into therapeutic agents are not permissible.

The outline of submission of foods for consideration by the Committee is sufficiently complete to guide manufacturers in submitting any type of food article. Submissions include samples, copies of all pieces of advertising, manufacturing formula, chemical analysis, information on micro-organisms to substantiate any special claims, specifications and definition of all raw material or ingredients used in preparation of the food, description of process of manufacture and packaging, and biologic vitamin assay in support of any special vitamin claims. The detailed information required is necessary for thoroughly and scientifically passing on each individual submission.

For its own guidance and that of food manufacturers and advertisers, the Committee is supplementing its rules and regulations by a series of General Committee Decisions on questions of foods and food advertising. The 38 decisions adopted to date have been published in booklet form which are distributed without charge, as are the Rules. The individual decisions define the Committee's opinion on nutritional and food issues of public import, on specific types of permissible and unpermissible advertising claims and names of foods, and on the proper and improper use of certain terms and phrases in advertising; they define the Committee's requirements for declaration of certain ingredients in specific foods and for the nutritional values and composition of certain classes of prepared foods. These decisions exemplify and illustrate the practical and explicit application of the Rules and Regulations to specific foods, to specific advertising statements, and to specific food problems.

A few of the briefer rulings are set forth below to exemplify their content:

Testimonials of a Medicinal or Therapeutic Character in Food Advertising.—Testimonials of a "health", medicinal or therapeutic character, or with such implication, in food advertising by persons unqualified to express a scientific authoritative opinion or judgment on the subject of the testimonial are misleading or deceptive and are not permissible. Testimonials accompanied by the writer's name and used with his permission will be considered as to their acceptability in individual instances.

Tonic Claims.—The term "tonic" or its inflected forms have vague and misleading meanings or implications in food advertising and are not permissible.

Fortification of Foods Other Than Table Salts with Iodine or Iodine Compounds.—The fortification of foods other than table salt with iodine or iodine compounds for dispensing additional food iodine to the public and supplementing that naturally present in foods is unnecessary and may lead to excessive iodine intake and endanger public health. Foods so fortified, other than table salt, will not be eligible for acceptance.

Sulphur Dioxide in Infant Foods.—Small quantities of sulphur dioxide are permissible in fruit products specially prepared for infants or children, provided the quantity does not exceed that compatible with good manufacturing practice in the preparation of the dried fruit used.

The wide range of the decisions is illustrated by the titles of others:

Academic Titles "Doctor" and "M.D." as Integral Parts of Names of Foods.
Ambiguous and Incorrect Use of the Term "Adequate" in Food Advertising.
Analytic Statements on Labels and in Advertising.
Chocolate and Cocoa Products: Special Recommendations for Children.
Constipation Statements in Lay Advertising for Roughage Foods and Bran.
"Digests Starch" Claim for Foods Containing Diastatically Active Malt or Malt Extract.
Feeding Formulas for Infants in Lay Advertising.
Food Advertising Claims with Scientific or Technical Significance.
Gelatin Not an Aid to the Digestibility of Milk and Milk Products.
Good Food Advertising.
"Health Food" Claims and the Term "Healthful."
Ideal Food Label.
Mastication Not an Aid to "Health" of Teeth and Gums.

Questionnaire Advertising.
"Sleep Inducing" Claims for Specific Foods.
So-Called Special "Diabetic Foods" or Special Foods for Sugar and Carbohydrate Restricted Diets.
Superlative and Comparative Claims.
Trick Claims in Food Advertising.
Uses of Terms "Sterile," "Sterilized" and "Sterilization."
Vague "Clinical Experience" Claims.
Vague Mineral Claims.
Vague Use of Terms "Balanced" or "Scientifically Balanced."
Vitamin Claims in Food Advertising.
Addition of Phenolphthalein, Acetylsalicylic Acid (Aspirin) and other Drugs to Chewing Gum, Candy and Food Articles.
Iodized Salt and Goiter an Iodine Deficiency Disease.
Vitamin and Mineral Content of Dried Vegetables.
Vitamin and Mineral Content of Sieved Fruits or Vegetables Recommended for Infants, Children and for Special Diets.
Vitamin Content of Prepared Fruit Juices; Liquid, Frozen or Dried.
Vitamin Content of Tomato Juice.
Vitamin Fortification of Foods.
Whole Wheat and Graham Foods.

These General Committee Decisions are being augmented as the work of the Committee progresses. They give exactness, permanence, and continuity to the Committee's judgments and work; they are for the explicit guidance and instruction of the food industry and advertising agencies. They are intended to so clearly distinguish between good and bad advertising that in the future it will not be possible for advertisers to plead ignorance as an excuse for incorrect and inappropriate advertising. The decisions are a part of the Committee's plan of operation to practically and constructively lead and advise the food industry in matters of foods and food advertising to the advantage of public health and welfare.

Experience is showing that the Rules and Regulations and General Committee Decisions are efficiently serving their intended purpose of instructing and familiarizing the industry in the fundamentals of good food advertising. They are serving as a guide in the preparation of new foods for the market, of new food labels, and of new advertising. They are instructing the food industry that it may better serve the public good in food merchandizing.

The Committee already has accepted 1,094 food products and rejected 41. Announcements of these acceptances and rejections are published in The Journal of the American Medical Association and include such descriptive information as should be helpful to persons interested in foods. The data in these announcements will be published later in one volume, "Accepted Foods." Information of this character is instructive to the public on the true nature and value of foods on the American market, and should puncture the sales value of exaggerated and inflated advertising frequently used to exploit the public.

From the start the Committee adopted a constructive advisory and educational program of operation. It was realized that only such a program in the field of food merchandizing could lead to the accomplishment of its purpose. The food laws penalize the offender but do not provide for directly aiding the law abiding; the law acts in a negative sense, its beneficence is indirect. The Committee chose to use its influence predominantly in the positive sense to identify and support those manufacturers who operate, to the best of their ability and understanding, to the mutual advantage of themselves and the public.

Food manufacturers are seeking an authoritative specialized unprejudiced guidance and leadership to meet successfully prevailing antisocial business practices. Food manufacturers are willing voluntarily to follow a leadership which they recognize as scientifically authoritative and equitable, free from political, industrial, or self-centered influences, in the movement of adopting sound business practices in the public's interest. Such leadership is offered by the Committee on Foods.

Food advertising apart from the container label is without the jurisdiction of food statutes. There has been no organized effective restraining force to discourage false advertising before the creation of the Committee. It is well recognized that all human agencies and activities require some sort of control. The most effective control originates with and is exercised by the controlled themselves. The Committee is undertaking its extraordinary task in the field of foods by instituting a system of self-control by which the food industry from within itself will be governed only by established knowledge, the welfare of the industry itself and the consciousness and recognition of public welfare. The goal can be achieved only by arraying certain available social and economic self-operative forces which by their very nature will mold merchandizing and advertising efforts in the public's interest. The demand for good advertising and meritorious foods will grow stronger as the industry and the public come to realize and enjoy their benefits. Good advertising will become generally established, and nutritionally desirable foods sought for when they are recognized and rewarded by buying support and penalized by lack of buying support. The Committee is committed to bring these social and economic forces into active play.

The forces of blame and praise, reward and punishment, must be released and active in the field of food merchandizing and advertising as elsewhere in society. These are the constructive social forces which support truth and the deserving but condemn falsity and the fraudulent; they are the forces which will effectively control the food industry and food advertising. Social and economic forces can be maneuvered and directed to the advantage of the socially high-minded and to the disadvantage of the socially low-minded. The need is for capable social engineers in the service of the public.

As previously stated the program of action of the Committee involves the positive aid of food manufacturers who are dedicated to sound business policies in the interest

of the public. These public spirited manufacturers may obtain the privilege of using the Committee seal on their products and in advertising complying with the Committee's requirements. The seal gives added potential sales value to accepted products which is not possessed by unaccepted competing products; it gives authenticity and trustworthiness to accepted advertising not possessed by unaccepted competitive advertising.

The Committee seal harnesses the active competitive forces in the business field to serve as control agencies in promotion of accepted foods of required food values and of good advertising. It is a constant reminder of truthfulness to the copywriter in the preparation of advertising; it exercises a restraining influence. An advertising agency is doubly cautious with advertising for accepted foods as criticism by the Committee of the advertising addressed to the client—the manufacturer—brings the work of the agency into question and jeopardizes its business standing. The seal therefore is a positive influence for the extension of good advertising. In these ways the conjugate influences of the seal and competitive forces work in the interest of better foods, better advertising, and the interest of the public.

The acceptance of foods in practically all cases follows more or less drastic changes in the labels and advertising. It is exceptional for a product to be accepted as submitted. In a large proportion of instances the labels and advertising are completely reconstructed. New tradenames are adopted for some foods. Manufacturing formulas of foods are being modified to satisfy the Committee's recommendations. The industry with fewer exceptions has been willing to comply with the Committee's requirements.

Subsequent to considering foods the Committee gives reasons for its decisions and recommendations, proposes means to meet its requirements, and the Committee's office discusses the Committee's findings and recommendations with the manufacturers that they may thoroughly understand the Committee's requirements and act intelligently and properly thereon. This is part of the Committee's constructive and educational program. This procedure establishes confidence in the Committee and gains the sympathetic support and good will of manufacturers. Understanding of the Committee's purpose and a sympathetic attitude on the part of the industry are essential to the success of the Committee.

It is intended that all highminded, worthy and socially responsible manufacturers will be supporters of the Committee and that the incapable and socially irresponsible only will be its opponents. It is a common occurrence for manufacturers to address letters of appreciation to the Committee after they have been put to the trouble and expense of altering labels and discarding advertising; they frequently acknowledge that the revised new labels and advertising, in addition to being correct and more appropriate, are improvements over the old labels and advertising for sales reasons. The response and reaction of the industry are highly gratifying.

THE ACTIVITIES OF CONSUMERS' ORGANIZATIONS

JAMES F. CORBETT*

Someone once said that if two people with the same idea get together in America, the result is an ORGANIZATION. Run your finger down the list of names of associations and societies in any almanac or directory and you will find Eagles, Owls, Elks and Moose, Dragons and Druids, National Associations of Manufacturers of everything from abacuses to zithers, but you will find very few groups whose work lies in the protection of the consumer or the advancement of his interests. Consumers in America (120,000,000 of them) are notoriously unorganized. This places them in a tremendously disadvantageous position in a democracy such as ours, where legislation is enacted in response to the demands of articulate groups capable of exerting economic and political pressure where it is most needed. It is estimated that there are well over 1000 trade associations ever active in Washington to give force and directness to the opinions and wishes of business. Yet there is probably no economic group in the country which is less adequately represented in the lobbies of our legislatures than the consumers.

The passage of the Food and Drugs Act in 1906 can be attributed to the efforts of certain public-spirited and fearless friends of the consumer such as the late Dr. Wiley and Professor Ladd, and the self-interest of farmer's organizations rather than to any organized activity on the part of consumers. The timely publication of *The Jungle* by Upton Sinclair did much to arouse public opinion, while the lobbies of the American Medical Association and the National Association of State Dairy and Food Departments were fighting the stand-patters in Washington. The crusade of the muckrakers against false and fraudulent advertising left a passing impression upon the public, soon to be forgotten as the great "Ballyhoo Age" descended upon us and muckraking was no longer profitable. In 1927 the apathetic public was again aroused when *Your Money's Worth* by Stuart Chase and F. J. Schlink described the waste of the consumer's dollar which resulted from his ignorance in purchasing goods in the new jungle of competitive advertising and powerful sales pressure, where the skillful

* B.S., 1925, College of the City of New York; M.A., 1930, New York University. Instructor in economics in a New York City high school. Assisted in the preparation of a prospective syllabus in Vocational Civics for New York City schools. Now engaged in the preparation of a study of consumption problems and their relation to education, and is collaborating on a new high school economics text emphasizing the development of social control.

presentation of misinformation with the aid of the latest psychology and pseudo-science, was forcing upon him all sorts of shoddy, adulterated and harmful goods at prices which reaped high profits for the producer. Soon a best seller, the book became a target for many bitter attacks by business and advertising men in the popular magazines. An attempt was made to pin the Bolshevik label upon it with the insinuation that the authors were inspired, if not subsidized, by the Third Internationale. One of the authors had previously organized a Consumers' Club to apply technological research to the qualities of foods, drugs, cosmetics, and other products. This organization grew rapidly and in 1929 became Consumers' Research, Inc., "a strictly non-profit, non-commercial, research and educational organization which studies and reports on goods and services from the point of view of their selection, purchase, and use by the ultimate consumer, and solely for the ultimate consumer's use and benefit." In four years the membership of subscribers, who pay an annual fee of $2.00, has grown from less than 1000 to some 45,000. New quarters where more extensive research facilities can be developed are now located in Washington, N. J.

The activities of Consumers' Research may be classified as (1) Testing and Advisory, (2) Educational, and (3) Legislative.

1. Testing and Advisory Activities.

In the four or five *Handbooks of Buying* which are sent to subscribers each year, several thousand products from alarm clocks to yeast are listed by *brand name* as recommended or not recommended. This advice is based upon actual test and research data or the authoritative and impartial opinions of governmental and private experts of known integrity. The following is a greatly condensed excerpt from one of the *Handbooks* and will give an idea of the material presented.

CANNED FRUIT FOR SALADS

Cans of mixed fruit for salads usually contain some discolored or mushy fruit, the individual taste of the various pieces is largely lost, and the bulk of the mixture usually consists of the cheapest fruit. Maraschino cherries, which are not recommended . . . are used. . . .

(A) Recommended

Commonwealth (dist. Commonwealth Packing Co., San Francisco) Not all firm, flavor good, 26c per lb. drained fruit.

(B) Intermediate

Del Monte (California Packing Corp.) Several minor defects. Flavor good, 19c per lb. drained fruit.

(C) Not Recommended

Kingko (King's County Packing Co., Oakland, Calif.) Some of fruit broken or mushy. Color and flavor good. 21c per lb. drained fruit.

Libby's (Libby, McNeill & Libby) Mushy pale fruit. Good flavor. 31c per lb. drained fruit.

Consumers' Research data shows that in many cases prices vary *inversely* with quality, and that, strange as it may seem to some people, prominent brands are often inferior. The *Handbooks* give authoritative information about diet, vitamins, canned and packaged foods, adulteration or false advertising of foods, drugs, antiseptics and cosmetics. In every case brand names are given since information of this sort without knowledge of the names of the products involved is only of academic value and can not be put to practical use by the consumer. The subscriber is pledged to treat most of the information regarding branded products as confidential, since the legal problem of possible libel or damage suits arising from criticism of such products has not yet been solved. However, Consumers' Research is now publishing a non-confidential bulletin in which such well-known products as Ambrosia, Clorox and Zonite Antiseptics, Vapex, Pebeco Toothpaste and Pepsodent Antiseptic are freely discussed and criticized.

2. *Educational Activities.*

The very nature of the confidential advisory service keeps the subscriber informed of the qualities and prices of goods, and the manner in which he can get more for his income. In the non-confidential bulletins, news of interest to the consumer is published. For example, in recent issues: a scientific discussion of athlete's foot, with the advice that proprietary drugs of secret composition such as Absorbine, Jr., Emerald Oil, and W. F. should not be used: a reprint from the Journal of the American Medical Association exposing the deception in the pseudo-scientific advertising of Scot Tissue. The *General Bulletin* has kept the consumer acquainted with the activity, and especially, lack of activity, of governmental agencies such as the Bureau of Standards, the Federal Trade Commission, and the Bureau of Mines, in serving the consumer-taxpayer. Laxity on the part of the Department of Agriculture and the Food and Drug Administration in actively enforcing the laws for the protection of the consumer has been severely criticized. Much of this information which was long familiar to Consumers' Research subscribers, was presented in a recent book by two members of the organization.

This book, *100,000,000 Guinea Pigs,* by Arthur Kallet and F. J. Schlink, has been a best seller for over six months. A large part of the public became familiar for the first time with the need for revising the food and drug laws and rebuilding the administrative machinery so that effective enforcement might be assured. In this book names were named and the apparently "reformed" drug, cosmetic, and food industries were brought out into the open, revealing fruits and vegetables contaminated with lead and arsenic from insecticide residues; poisonous cosmetics; worthless antiseptics; inert ergot and sub-standard ether; emasculation of the protective features of the Food and Drugs Act for the benefit of food and drug purveyors.

3. *Legislative Activities.*

Although Consumers' Research cannot support a lobby in the state capitols or at Washington, it has long maintained that only through effective organization can

the consumer secure protection. "Producers Organize—Consumers Must." Consumers' Research keeps in touch with legislators who are sympathetic with the consumer's interest and supplies them with needed data to remedy existing legislation, strengthen administrative procedure, or combat bills or rulings which are opposed to the consumer's welfare. Students of the food and drug problem and trade papers in the industries attribute the present widespread demand for sweeping changes in the Food and Drugs Act, and for a radical change in the administration of the law, to the Bulletins and activities of Consumers' Research and particularly to the public indignation which has followed the exposures in *100,000,000 Guinea Pigs.* A barrage of criticism has been continuously laid down against the rulings and methods of the Food and Drug Administration which has been sympathetic toward the big business viewpoint which, in meeting the stockholders' demand for dividends, too often places profits above the health or welfare of the trusting consumer. Consumers' Research has long advocated administration of the laws by scientists and technologists like the late Dr. Wiley, rather than by lawyer-politicians; supervision of advertising which now runs hog-wild and scotfree; a system of frank and full publicity for all aspects of food, drugs, and *cosmetic* regulation. This organization is now sponsoring new legislation in New York State and, as the Chairman of the Senate Committee on Public Health stated to the writer, is the only group to show any interest in the movement for better food and drug laws.

Consumers' Research, in 1932, helped oppose the passage of the Capper-Kelly Bill[1] which would have enabled manufacturers to fix the prices at which their products could be sold at retail. The only other organization representing the consumer at the hearings was the American Home Economics Association. This organization of 10,000 teachers of home economics was founded in 1908 and has been largely responsible for the advance in home economics education which has taken place in the United States. The *Journal of Home Economics* which the Association publishes, has never been critical of the Food and Drug Administration and has often carried articles which are manifestly propaganda of the Administration itself or of food manufacturers. In the field of textiles and household equipment, however, the Association has taken a more aggressive stand. In coöperation with the American Standard Association, which is dominated by business interests, an attempt was made to set up quality standards for, and require informative labeling on such products as blankets, sheets, silk, and refrigerators. The opposition of the manufacturing representatives who dominated the conferences, was strong enough to sabotage the program, and the consumer can read the labels today and be just as ignorant as he ever was regarding the quality of the merchandise.

Much has been written in the *Journal* about improving school courses of study in home economics, but today cooking and sewing still predominate in the curriculum. With business men on boards of education clamoring for retrenchment,

[1] 72nd. Cong., 1st. Sess., S. 97 (1932).

and the elimination of what they are pleased to call the "fads and frills," home economics teachers are having a hard enough time holding on to their jobs, and little is being done to furnish useful buying information in the schools. Some of the research conducted by home economists in such diet problems as vitamins, has been useful, but it is very soon perverted into misinformation by the advertisers of drugs and food products who often employ home-economists to achieve this end. Much of the research is devoted to the solution of such burning problems as the "Factors Controlling Internal Temperatures of Butter Cakes During Baking."

The National Consumers League has for its purpose the protection of the worker through the coöperation of the consumer. Although it participated in the great crusade of 1906, this organization has been more prominent in securing shorter hours and decent working conditions for women and children. The Coöperative League of the U. S. A. hopes to protect the consumer through a reorganization of society and the "ownership of industry by voluntary associations, consisting of consumers, run by consumers, functioning for consumers." Through their national periodical *Coöperation* they keep their members informed of the difficulties of the consumer in the present market, but like the Consumers' League, they have not taken any active part in establishing standards for foods and drugs or sponsoring and demanding increased protection through legislation.

One might expect that women's organizations would be particularly active in lobbying for more adequate protection of consumers, but their work has not been very effective in this field. Nearly thirty years ago, energetic Miss Alice Lakey swung the forces of the General Federation of Women's Clubs into line to fight for the pure food lobby. Since then, with an estimated membership of over two million they have carried on a modest program, in coöperation with the American Home Economics Association and the Bureau of Home Economics, to encourage its members to study the problem of household purchasing. The total result of such programs seems to be a realization on the part of these women that it is almost hopeless to buy intelligently with the present information available to the housewife. The Association of University Women, with a present membership of about 40,000 is also helping to spread information on consumers' problems through its *Journal* and other publications. An organization which might be particularly effective if it ever decided to marshal its strength on the side of the consumer, is the Women's Joint Congressional Committee. Since 1923 it has been composed of seventeen national women's organizations. In 1923 they secured the passage of new legislation regulating interstate and foreign commerce in livestock and other agricultural or dairy products, and prohibiting commerce in "filled" or adulterated milk. Their interest, however, has been largely in other fields, such as women's rights, child welfare, and social hygiene.

It is difficult for such consumer organizations to become an effective pressure group, either as a legislative lobby, or a propaganda agency. It is next to impossible

to secure a large endowment in America for any work which will conflict with the wishes of organized business. In the case of women's organizations, most of their funds come from members or friends whose interests must be on the producer's side, although it is of course quite possible that one of these days a philanthropist may appear who is disinterested enough to leave part of a fortune for work to be carried on in the interest of consumers. In addition, the members of women's clubs or associations often find that their own sympathies can not be wholeheartedly with the consumer. The economic interests of other members of their families, or of the group itself, will promptly inhibit any militant impulse to attack local or national business too strenuously. There are strong social as well as economic bonds to be considered—and houses divided against themselves make poor lobbies.

As for propaganda: public opinion is controlled largely through the press and the radio, and these are not anxious to be too offensive to advertisers. The schools are having their troubles in securing enough money to keep open. Progressive educators may desire to impart information in the class room, but as Professor Lynd very tactfully puts it in *Recent Social Trends* with scholarly caution and avoidance of controversy: "even . . . adventurous school systems encounter . . . the tactical difficulty of using such data, even when available, in a local community living by competitive merchandising."[2]

If consumers are to get together for their own protection (and they certainly need to today) an organization such as Consumers' Research, Inc., seems to be the most likely type about which the movement can grow. Its integrity has never been questioned by informed people, its steady growth indicates that it is meeting a need which consumers really feel, and its program and policies are practical and militant rather than visionary, weakly liberal, or utopian. The consumer is supposed to be represented in the National Recovery Administration by a Consumers' Advisory Board. The extent to which this board has represented him has been dramatically disclosed by the front page news of the resignation of the famed sociologist, Professor Ogburn, who declared that "the weakest link [in the recovery program] is the provision for protection of consumers," that there was no strong organization represented to fight the consumers' case, and that no adequate attempt has been made to gather facts or establish standards relating to price and quality.

It is apparently time for a strong consumer organization to take a hand in the new deal. The cards must be played with great skill because 1000 trade associations consider consumer ignorance and disorganization a vested interest to be retained at all costs.

[2] Lynd, *The People as Consumers*, 2 RECENT SOCIAL TRENDS (1932) 857, 882.

A NOTE ON THE CIVIL REMEDIES OF INJURED CONSUMERS

ALBERT H. COTTON*

From the beginning of the common law, the problem of protecting the consumer from losses caused by defects in food and drugs has faced the courts. While customers have cried to them for protection, business men, probably from the beginning of trade, have lamented that such liability would ruin their business. In dealing with this problem the courts have reflected the spirit of their times. The result has been a changing body of law, and "because the struggles are not wholly over, because the confusion partly still persists, the study of this history has peculiar present value."[1]

The first approach to the problem in English law was preventive rather than remedial. In medieval times markets were strictly regulated in the interests of the consumers. Regulations extended even to price. They were local and enforced in the local courts. The proceedings were criminal in nature, designed not only to prevent impure foods but unworthy products of all kinds from coming to the market.[2] There were in addition extra-legal penalties which must have been a powerful deterrent to selling defective goods. The butcher's, the greengrocer's and the apothecary's shops were strictly neighborhood institutions, and the sickness of a customer, whose illness, as all the customers knew, was caused by something purchased at a local shop, would lead to financial losses more terrifying to the proprietor than a judgment for damages. However, the dealer had a real opportunity for knowing what he was selling. His goods were purchased locally and in bulk. These extra-legal safeguards have almost entirely disappeared today. A sick customer means little to a national chain store, or to a national manufacturer of food or drug products, unless and until his lawyer appears. And the dealer, in so far as his stock comes in packages or cans, has no more opportunity than the customer to know what he is selling.

The older local regulations broke down with the decline of the social system in which they were born and the decay of the local courts in which they were enforced, but as early as the reign of Henry III[3] Parliament began passing Statutes of the Realm

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[1] LLEWELLYN, CASE AND MATERIALS ON SALES (1930) 204.

[2] Hamilton, *The Ancient Maxim of Caveat Emptor* (1931) 40 YALE L. J. 1133.

[3] 51 HEN. III, C. 6, §3 (1267) S. (" *'pillor', et tumbrel', et assiss' panis et cervis'* ").

regulating victualers and others of much the same character. A civil remedy was given the injured party by the courts, on the ground that the dealer had violated a statute for the protection of the public.[4] Moreover, with the development of the remedy of assumpsit in the King's courts an additional[5] basis for the obligation to sell pure food and drugs was found in the view that the "common victualer," in opening his shop, had undertaken the obligation to provide food fit to eat to his customers, which became an implied term of his contract.[6] Cases before 1800 are scarce, but it appears that recovery must have been unusual. Injuries may have been unusual also. Although the concept of the "common calling," originally applicable to all who held themselves out to do business with the public, is a narrowly restricted term today, an English decision as late as 1847[7] limited recovery for defective food, in the absence of express warranty or fraud, to suits against dealers, as an obligation incident to their calling.[8]

With the coming of the industrial revolution and its accompanying accentuation of individualism, *caveat emptor* replaced the doctrine of the common calling, especially in American courts,[9] and protection for consumers of food and drugs was a matter of exception to be granted guardedly. Thus, though Blackstone[10] had recognized an implied warranty of fitness where food was sold, the Massachusetts court in 1813[11] interpreted him to mean this to apply only where a dealer *knew* that he was selling impure food, and disguised it, a construction which appears to unduly limit Blackstone's text.[12]

The common law rules governing the liability of sellers, as they are applied today, were worked out chiefly in the nineteenth century by the same courts which were devising that harsh body of rules governing actions for personal injuries to employees which has since been swept away by workmen's compensation statutes. The spirit of the law was opposed to the imposition of liabilities which might handicap the expansion of business.[13] Courts were slow to "imply" contractual undertakings not expressed by the parties. Liability without fault was a submerged concept in the law of torts.

[4] *Cf.* discussion of early law by Parke, B., in Burnby v. Bollett, 16 M. & W. 644, 654, 153 Eng. Repr. 1348, 1352 (1847).

[5] Warranty actions were first brought in tort for deceit but later assumpsit, a contract action, was used. AMES, LECTURES ON LEGAL HISTORY (1913) 136-138.

[6] Burdick, *The Origin of Duties Peculiar to Public Service Corporations,* (1911) 11 COL. L. REV. 514.

[7] Burnby v. Bollett, *supra* note 4.

[8] In Emmerton v. Mathews, 7 H. & N. 586, 158 Eng. Repr. 604 (1862), recovery was denied in a suit between dealers because it was not shown the seller knew his meat was defective, but recovery was allowed in Bigge v. Parkinson, 7 H. & N. 955, 158 Eng. Repr. 758 (1862), where plaintiff was a customer who relied on the dealer to pick out food products to be used as food for troops. There was an express warranty that the food should pass East India Company inspection, but the court said this did not negative implied warranty of fitness for food purposes.

[9] Hamilton, *supra* note 2, at 1178.

[10] 3 BLACKSTONE, COMMENTARIES, *165.

[11] Emerson v. Brigham, 10 Mass. 197 (1813).

[12] "In contracts for provisions it is always implied that they are wholesome, and if they are not the same remedy may be had." 3 BLACKSTONE, *supra* note 10.

[13] BOHLEN, STUDIES IN THE LAW OF TORTS (1926) 129.

There were three legal theories available for the protection of the consumer. First, the seller could be held liable because he contracted to supply a good article (either on an express warranty or an implied warranty of fitness or merchantability) and broke his contract. Second, the party responsible for the impurity could be held for negligence in permitting or causing its existence, where this negligence was the proximate cause of the injury. Third, if the dealer knew of the defect, he could be held liable in the tort action for deceit, a remedy of little value to the consumer because of the difficulty in proving the dealer's knowledge.

The first is best exemplified today by the Uniform Sales Act, providing that (1) where the buyer expressly, or by implication, makes known to the seller that he relies on his skill and judgment in the purchase of goods for a particular purpose, there is an implied warranty of fitness for that purpose, and (2) where the buyer purchases from a dealer "by description" there is implied warranty of merchantability.[14] By further providing for the implication of these warranties regardless of whether the seller was a grower or manufacturer, the act brushes aside a limitation of such liability to those classes existing in a minority of American jurisdictions.[15] Indeed, in some states, the implied warranty of merchantibility was not recognized, and only recently has it been realized that in food cases, at least, it may be coextensive with the warranty of fitness for food purposes.[16] This fact may be of special significance when the housewife orders by brand name, as she is urged to do in page after page of national advertising, for the Sales Act, in accordance with decisions preëxisting it, excludes the warranty of fitness in that situation.[17] But the warranty of merchantability, which may then be turned to, applies only to sales "by description." Where the purchaser instead of ordering, herself selects an article from a counter, it is doubtful whether the sale would be "by description," a loophole rendered important by some modern chain-store merchandizing practices.[18] Moreover, it is doubtful whether the "description" is not satisfied where the entire brand is not "merchantable" (as may not be unlikely in the case of some proprietary medicines).[19]

Inspection by the purchaser will defeat recovery for defects that such examination should have revealed, a limitation whose uncertainty in application invites litigation.[20] Where, as in the case of canned goods, it is obvious that the dealer has no knowledge of the quality of the goods he sells, some courts have denied recovery to

[14] Uniform Sales Act, §15.

[15] 1 Williston, Sales (2d ed. 1924) 451.

[16] See Cardozo, C. J., in Ryan v. Progressive Stores, 255 N. Y. 388, 392, 175 N. E. 105, 106, 74 A. L. R. 339, 341 (1931).

[17] Uniform Sales Act, §15 (4).

[18] It is to be hoped that this differentiation is too fine-spun to be followed by a court. But the rule is that where the purchaser picks out the goods herself, there is no implied warranty. Farrell v. Manhattan Market, 198 Mass. 271, 84 N. E. 481, 15 L. R. A. (N. S.) 884 (1908).

[19] Note (1932) 45 Harv. L. Rev. 1415.

[20] It becomes a question of fact for the jury. Friend v. Child's Dining Hall Co., 231 Mass. 65, 120 N. E. 407, 5 A. L. R. 1100 (1918); Farrell v. Manhattan Market, *supra* note 17.

the buyer on the ground that he could not have relied on the seller's "skill and judgment."[21]

The intricacy of these rules, the unimportance of the factual differentiations upon which they are based, stand in sharp contrast to the informality of the normal retail transaction in which neither party knows or considers these legal consequences of his acts whose sequence may well be wholly fortuitous. Indeed, there is little likelihood that they will be accurately recalled when pending litigation and conferences with counsel reveal their significance. It is difficult to avoid the suspicion that the rules of the Sales Act were framed with more concern for wholesale transactions than for the over-the-counter retail purchase or the domestic order placed by telephone.[22]

But a still more serious limitation on the efficacy of the law of warranty as a means of consumer protection lies in the fact that neither the benefit nor the burden of the warranty "runs with the goods." It benefits only the purchaser, in principle and by the weight of authority, yet the whole family, their guests and servants may eat the defective food. Lack of privity of contract will prevent a recovery by the guests and servants, since the action on this theory must be on the contract.[23] The husband can recover on grounds of agency where his wife or child was the purchaser,[24] and if either of them suffers injury he may, perhaps, obtain damages for the loss of consortium or services and for the cost of medical care furnished them.[25]

Since the retail seller may frequently be judgment-proof, ingenious efforts have been recently made to hold manufacturers or distributors as express warrantors, by virtue of advertising or labels.[26] A manufacturer has been held liable to the final purchaser of an automobile, on the ground that his advertisement of "Shatter-proof" glass was an express warranty,[27] and in Mississippi the manufacturers of "Baby Ruth"

[21] Kroger Grocery Co. v. Lewilling, 165 Miss. 71, 145 So. 726 (1933); Bigelow v. Maine Central R. R., 110 Me. 105, 85 A. 396, 43 L. R. A. (N. S.) 627. *Contra:* Ward v. Great Atlantic & Pacific Tea Co., 231 Mass. 90, 120 N. E. 225, 5 A. L. R. 242 (1918). The view that the dealer is not a warrantor seems to fly in the teeth of the wording of the Sales Act.

[22] Even the rules of the Sales Act, in force in 30 states, are more favorable to consumers than the common law rules of some states governing warranty. 1 WILLISTON, *op. cit. supra* note 15, at 499. "Remedies of injured consumers ought not to be made to depend on the intricacies of the law of sales. . . . It should rest . . . upon 'the demands of social justice.' " Ketterer v. Armour, 200 F. 322, 323 (S. D. N. Y. 1912) (holding manufacturer liable to consumer in tort).

[23] 1 WILLISTON, *op. cit. supra* note 15, at 487. *Contra:* Davis v. Van Camp Packing Co., 189 Iowa 775; 176 N. W. 382, 17 A. L. R. 649 (1920); Hertzler v. Manshum, 228 Mich. 416, 200 N. W. 155 (1924).

[24] Ryan v. Progressive Stores, *supra* note 16.

[25] Kennedy v. Woolworth, 205 App. Div. 648, 200 N. Y. Supp. 121 (1923) (child). *Contra:* Rode v. Arney, 115 Ill. App. 629 (1904) (husband cannot counterclaim for loss of wife's services, in suit on notes given for defective wagon, which broke, injuring wife). The general rule is that plaintiff who is in privity of contract and thus a party to the warranty, can recover damages which are the natural consequences of the defect. 2 WILLISTON, *op. cit. supra* note 15, at 1542. But the child, Redmond v. Borden's Farm Products Co., 245 N. Y. 512, 157 N. E. 838 (1927), the wife, Gearing v. Berkson, 223 Mass. 257, 111 N. E. 785, L. R. A. 1916D 1006 (1915), and the servant, Chysky v. Drake Bros., 235 N. Y. 468, 139 N. E. 576, 27 A. L. R. 153 (1923) cannot recover in their own names in a warranty suit.

[26] 1 WILLISTON, *op. cit. supra* note 15, at 490, Sholley, *Manufacturer's Advertisement as Express Warranty* (1932) 7 WASH. L. REV. 351, Llewellyn, *op. cit. supra* note 1, at 389.

[27] Baxter v. Ford Motor Co., 168 Wash. 456, 12 P. (2d) 409 (1932). The court said, p. 412, "Since the rule of caveat emptor was first formulated, vast changes have taken place in economic structures of

candy bars have been held to an implied warranty, on the basis of advertising, despite the privity of contract rule.[28] But in earlier cases where the same argument was attempted a manufacturer of bread in which a pin was found was held not liable, even though he labeled the bread "guaranteed after thorough inspection," since the guarantee was construed to apply only to the purity of ingredients used, and not to be a guaranty against the presence of foreign matter, a tenuous distinction.[29]

But regardless of whether there is a warranty, if negligence can be proven there can be a recovery, and it is in actions based on this theory that the manufacturer or distributor can best be reached and that the injured non-purchaser may obtain compensation.[30] Even this liberality represents an exception in the rule that there must be privity of contract for recovery against a manufacturer of goods, even in tort actions.[31] This notion entered tort law through the concept proximate cause, with the idea that the intermediate sale broke the chain of causation. Until the day of packaged goods and national advertising, moreover, the purchasers' actual protection was probably the dealer's judgment and inspection. But in the United States, this limitation has not been applied in favor of negligent manufacturers of food and drugs since the case of *Thomas v. Winchester*[32] in New York in 1852. Here a recovery was allowed against a manufacturer who mislabeled a drug negligently, where the plaintiff was a consumer without contractual relations. This rule is followed in all common-law jurisdictions, although it was not adopted by the House of Lords until 1932, and then only with vigorous dissent, in a case where a mouse was immured in a ginger-beer bottle.[33].

The difficulty in proving negligence in these cases is a formidable obstacle. The

the English speaking peoples. Methods of doing business have undergone a great transition. Radio, billboards and the products of the printing press have become the means of creating a large part of the demand that causes goods to depart from factories to the ultimate consumer. It would be unjust to recognize a rule that would permit manufacturers to create a demand for their products by representation that they possess qualities which they in fact do not possess, and then, because there is no privity of contract existing between the consumer and manufacturer, deny that consumer the right to recover if damage results from the absence of those qualities when such absence is not readily noticeable."

[28] Curtiss Candy Co. v. Johnson, 163 Miss. 426, 141 So. 762 (1932). The court here holds there is an implied warranty by a manufacturer of food products on which the consumer can sue, relying on defendant's advertising, and also holds that dealers, with no opportunity to examine the contents of the package, are not liable as warrantors.

[29] Pelletier v. Du Pont, 124 Me. 269, 128 A. 186, 39 A. L. R. 972 (1923).

[30] Broadway v. Grimes, 204 N. C. 623, 169 S. E. 194 (1933). The superiority of the remedy on the warranty, where available, is shown by two Massachusetts cases, on practically identical facts, where the counsel who brought his action on the contract won, Friend v. Childs Dining Hall Co., *supra* note 19, and the counsel who sued in tort failed for failure of proof of negligence, Ash v. Childs Dining Hall Co., 231 Mass. 86, 120 N. E. 396, 4 A. L. R. 1556 (1918). See note (1918) 33 HARV. L. REV. 241. Some states where the vendor is a restaurant deny liability on a warranty entirely, on the ground that services, not goods, are being sold. I WILLISTON, *op. cit. supra* note 15, at 485.

[31] MacPherson v. Buick Motor Co., 217 N. Y. 382, 111 N. E. 1050 (1916) BOHLEN, *op. cit. supra* note 13, 109.

[32] 6 N. Y. 397 (1852).

[33] M'Alister v. Stevenson [1932] A. C. 562. Lord Atkin concluded his opinion, "It is a proposition which I venture no one in Scotland or England who is not a lawyer would for one moment doubt. It will be an advantage to make clear that the law in this matter as in most others is in accordance with common sense."

plaintiff may often be exposed to a non-suit or a directed verdict against him for want of sufficient evidence to establish it. The rule of tort law, that where normally an injury would not occur without negligence and where the means of preventing it or explaining its cause are exclusively within the control of the defendant, the plaintiff need not introduce evidence of negligence, would afford him some protection from this hazard if it were applied here, yet this doctrine of *res ipsa loquitur* has been applied to food and drug cases by only a minority of jurisdictions.[34] Its rejection is mitigated in other jurisdictions by the fact that evidence of the presence of a foreign substance in food and drugs establishes a prima facie case.[35] Moreover, in those cases where the question is submitted to the jury, jurors are permitted to use their own experience and reasonable inferences in deciding whether impurities entered through the negligence of the manufacturer in jurisdictions which follow neither the *res ipsa loquitur* nor the *prima facie* rule.[36]

Violation of a pure food and drug act has been held sufficient to show negligence and permit a recovery since these statutes are enacted for the public's protection from the very harm suffered.[37] Consequently, if the pure food and drug act is made broad enough, the difficulties of proof in negligence actions largely disappear. The New York Farm and Markets act, for example, has been applied to permit a recovery where there was no privity of contract under holdings that it was negligence as a matter of law to market impure poultry feed, since it was prohibited by statute.[38] In a later decision the New York Court of Appeals expressly left open the question of the application of this statute to a purchase of bread.[39] Yet the use of such statutes for this purpose is perhaps the only device that is broad enough to give customers sufficient protection under modern marketing conditions, where goods are bought in packages whose past history may be undiscoverable, where customers cannot tell

[34] Schneider, *Presumptive Rule of Negligence* (1933) 13 B. U. L. REV. 50, 58.

[35] Cases on the problem are collected in Notes (1919) 4. A. L. R. 1559 and (1927) 47 A. L. R. 148. The Massachusetts rule in Ash v. Childs Dining Hall Co., *supra* note 29, is criticized as making proof too difficult for the injured plaintiff in 5 WIGMORE, EVIDENCE (2d ed. 1923) 496.

[36] Tonsman v. Greenglass 248 Mass. 275, 142 N. E. 756 (1924), Minutilla v. Providence Ice Cream Co., 50 R. I. 43, 144 Atl. 884, 63 A. L. R. 334 (1929).

[37] Meshbesher v. Channellene Oil & Mfg. Co., 107 Minn. 104, 119 N. W. 428 (1909); Kelley v. John R. Daily Co., 56 Mont. 63, 181 Pac. 326 (1919); Armour v. Wannamaker, 202 Fed. 423 (C. C. A. 3d, 1913). In South Carolina there is confusion. *Cf.* Tate v. Mauldin, 157 S. C. 392, 154 S. E. 431 (1930), and Burnette v. Augusta Coca-Cola Bottling Co., 157 S. C. 359, 154 S. E. 645 (1930), with Culbertson v. Coca Cola Bottling Co., 157 S. C. 352, 154 S. E. 424 (1930). The tendency of the courts is to use the pure food laws as a makeweight, after finding a common law or statutory sales law ground for liability in warrantory or tort. *Cf.* Mazetti v. Armour & Co., 75 Wash. 622, 135 Pac. 633, 48 L. R. A. (N. S.) 213, (1913) Ward v. Morehead City Sea Food Co., 171 N. C. 33, 87 S. E. 958 (1916) (a distinct ground of decision, but not mentioned in later North Carolina cases) and Ryan v. Progressive Stores, *supra* note 16, where the New York court found it unnecessary to inquire if the statute applied. The pending Copeland Bill, 73rd Cong., 1st. Sess., S. 1944, §24, gives a civil remedy to all persons for injuries or death resulting from violation of the Act, but this result would probably follow in any event. This theory has not been of greater use in the past, perhaps, because pure food laws either required knowledge as an essential element of violation or were limited in scope.

[38] Pine Grove Poultry Farm v. Newton By-Products Co. 248 N. Y. 293, 162 N. E. 84 (1928).

[39] Ryan v. Progressive Stores, *supra* note 16.

when they buy whether or not the goods are wholesome, and where the local dealer knows little more than they do, and in addition is probably near insolvency.

Another solution would be to make all dealers and manufacturers of food and drugs insurers of wholesomeness, which is done in some jurisdictions in the case of restaurants.[40] But the courts could scarcely do this without legislation, and pure food and drug legislation, construed with the same solicitude for human consumers as was the New York Farm and Markets Act for poultry, would achieve the same beneficial result. A further possibility for a remedy against a manufacturer lies in holding that his warranty to the dealer is a contract on which the consumer may sue as a third party beneficiary.[41]

The recent increase in cases of food and drug injuries indicates, however, a need for protection against hold-up suits as well as for protection for the helpless consumer. This protection is supplied in theory at least by requiring a connection between the impurity in the food or drug and the injury. Medical testimony may be relied on for this.[42] The courts will even consider the state of the consumer's health as described by his application for life insurance.[43] Contributory negligence is a defense in a negligence action, and a consumer cannot recover for injury, even in warranty, if he deliberately ate bad food after discovering the defect. Damages for fright and shock, unless the fright causes a physical injury, are not allowed,[44] and thus a fruitful source of hold-up suits is stopped. Manufacturers and dealers may, moreover, spread the losses resulting from impure products, through insurance or through raising their price level slightly. The injured consumer cannot anticipate his loss or minimize its consequences, except by a recovery against dealer, distributor or manufacturer. Imposition of liability will tend to make tradesmen careful.

In the hands of a court imbued with the idea that the common law can change to meet changing conditions, and firmly convinced that conditions have changed greatly since the days when the obligations of sellers became fixed, the common law remedies for injured consumers can prove adequate. But today the injured persons face rather the possibility of a test case, for the more stringent rules imposing liability are not yet decided law in most jurisdictions, and besides the aid of an able physician to heal his injuries, he must have an able and industrious attorney to chart his way through the maze of conflicting theories and old precedents which may operate to bar him from damages. But the average injured consumer is not equipped for such legal battle. Like the average injured employee, or victim of an automobile accident, he needs a clear law, imposing liability, which will induce those who supplied him with food or drugs to settle quickly, rather than the chance that the court will, consciously or unconsciously, change the law to meet changed conditions.

[40] Smith v. Carlos, 215 Mo. App. 485, 247 S. W. 468 (1923).
[41] Ward Baking Co. v. Trizzino, 161 N. E. 557 (Oh. App., 1928).
[42] Harper v. Bullock, 198 N. C. 448, 152 S. E. 405 (1930).
[43] McCabe v. Pennsylvania R. Co., 311 Pa. 229, 166 A. 843 (1933).
[44] Kenney v. Wong Len, 81 N. H. 427, 128 A. 343 (1925). The rule in some states that there can be no recovery for fright unless it is accompanied by physical injury would apply in these cases.

THE PROPOSED FOOD AND DRUGS ACT: A LEGAL CRITIQUE

MITCHELL SALEM FISHER*

The proposal for a new federal Food and Drugs Act[1] is but another phase of increased interest on the part of the Roosevelt Administration in the problems of the purchasing public, an interest already evinced by the National Securities Act.

The task of the present article is not to venture a study in ethics nor in the factual background of food and drug legislation nor even to wage polemics on behalf of the proposed bill. The object of this study is more mundane: to view the bill in its relation to the present federal Food and Drugs Act[2] and to speculate with legal

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The writer wishes to acknowledge his great indebtedness to Miss Esther Oshiver, recent graduate of the University of Pennsylvania Law School, for her extensive and helpful research into the field of food and drug control by the several states and the question of civil liability for violation thereof. Only his modest disregard of his extensive and valuable critical labors on the manuscript has prevented the name of Professor Milton Handler, counsel to the National Labor Board, being added as a co-author. The writer, however, takes sole responsibility for the positions assumed with regard to the bill. Acknowledgement is made to the Columbia Law Review for permission to use in part the writer's legislation note, *The Consumers' Protection under the Federal Pure Food and Drugs Act* (1932), 32 Columbia Law Review, 720.

[1] S. 1944, 73rd Cong. 1st Sess. (1933). The bill was introduced by Senator Copeland and referred to the Committee on Commerce. H. R. 6110, 73rd Cong. 1st Sess. (1933) introduced by Congressman Sirovitch parallels the Copeland bill with the exception of Section 3 which requires that all drug containers shipped in interstate commerce must have a label bearing a registered trade mark and attempts in other ways to use the trade mark method for securing disclosure of ingredients.

Throughout this article, wherever reference is made to the "bill," the Senate bill is intended. "Act" (unless otherwise qualified) will mean the present law. For discussion of S. 1944, see Tugwell, *The Copeland Bill and the Food Industries*, GROCERY TRADE NEWS, Oct. 24, 1933; Campbell, *A New Food and Drugs Act* (1933) 17 U. S. DEPT. AGR. FOOD REV., No. 7; Handler, *Revision of Federal Food and Drugs Law*, OIL, PAINT AND DRUG REP., June 26, 1933, at 17; *Analyzing the New Drug Act*, DRUG AND COSMETIC INDUSTRY, Aug. 1933.

[2] 34 STAT. 768 (1906), amended by 37 STAT. 416 (1912), 37 STAT. 732 (1913), 41 STAT. 271 (1919), 42 STAT. 1500 (1923), 46 STAT. 1019 (1930), 21 U. S. C. A. §§1-15, §10(5) (Supp. 1932). The Act and its amendments, the Rules and Regulations (Ninth Revision) issued thereunder, the Regulatory Announcements, Definitions and Standards, the more important Food Inspection decisions, and texts of related federal and state statutes are collected in 1 DUNN, FOOD AND DRUG LAWS (1927) (Supp. 1929). The Rules and Regulations will be noted as "Reg."; Regulatory Announcements, as "Reg. Ann."; Food Inspection Decisions, as "F. I. D."; and Notices of Judgment, as "N. J."

technology concerning its scope, limitations, validity and effect. Such an analysis is of particular importance in view of the fact that the present form of federal legislation on the subject which was enacted in 1906 in response to the demand for wider federal action[3] rapidly became the prototype for state enactments[4] and the probability that the present bill, if passed, will similarly serve as a model for future food and drug regulation in the various states.

BASIS OF VIOLATION UNDER THE PRESENT ACT

Contrary to popular conception, the Act as now phrased does not directly penalize misbranding and adulteration.[5] It attempts regulation by indirection, *i. e.*, it closes the stream of foreign and interstate commerce to both misbranded and adulterated articles of medicine and food. Until a shipment occurs, no violation is possible, despite the fact that articles designed for interstate commerce may have been adulterated or misbranded. For with the exception of the provisions governing the District of Columbia and the territories[6] the Act controls only transportation, forbidding the shipment or delivery for shipment in interstate commerce, or the receipt and delivery (or offer of delivery) in original unbroken packages after an interstate jour-

[3] For a history of early legislation on foods and drugs in America and the agitation leading up to the law, see WEBER, THE FOOD, DRUG, AND INSECTICIDE ADMINISTRATION, ITS HISTORY, ACTIVITIES, AND ORGANIZATION (1928); Dunn, *History of United States Food Laws* (1926) 21 AM. FOOD J. 564; Conover, *National, State, and Local Coöperation in Food and Drug Control* (1928) 22 AM. POL. SC. REV. 910; *The Laws That Govern Drugs,* AM. DRUGGIST, Oct. 1933, at 88. See also Maxey, *Federal Quarantine Laws* (1909) 43 AM. L. REV. 382.

[4] See Conover, *supra* note 3, at 913; Holt, *Uniform Legislation* (1927) 22 AM. FOOD J. 3; *Legis.* (1931) 31 COL. L. REV. 872, 873 n. 8. The existence of the Act invalidated a state law in only the one instance where the state statute was interpreted as necessarily calling for the removal of the federal label. McDermott v. Wisconsin, 228 U. S. 115, 33 Sup. Ct. 431 (1913). See Note (1913) 27 HARV. L. REV. 75. Unless thus directly interfering with the enforcement, Congress has not so "occupied" the field that the state may not prescribe additional standards of purity for the privilege of retail sale [Savage v. Jones, 225 U. S. 501, 32 Sup. Ct. 715 (1912); Hebe Co. v. Shaw, 248 U. S. 297, 39 Sup. Ct. 125 (1919); Armour & Co. v. North Dakota, 240 U. S. 510, 36 Sup. Ct. 440 (1916)] even though the sale be made in the original packages. Standard Stock Food Co. v. Wright, 225 U. S. 540, 32 Sup. Ct. 784 (1912); Corn Products Refining Co. v. Eddy, 249 U. S. 427, 39 Sup. Ct. 325 (1919). The mere fact that a state statute follows *mutatis mutandis* the federal Act is not determinative. Corn Products Refining Co. v. Eddy, *supra,* at 438, 39 Sup. Ct. at 330. Nor does the federal Act interfere with supplementary legislation by insular possessions. Gonzalez v. People of Porto Rico, 51 F. (2d) 61 (C. C. A. 1st, 1931). Compliance with federal standards does not secure the right to interstate transportation free from "reasonable" regulation by the state. Sligh v. Kirkwood, 237 U. S. 52, 35 Sup. Ct. 501 (1915); Weigle v. Curtice Bros. Co., 248 U. S. 285, 39 Sup. Ct. 124 (1919); see Note (1921) 19 MICH. L. REV. 739. Municipal ordinances do not interfere. See E. Fougera & Co. v. City of New York, 224 N. Y. 269, 280, 120 N. E. 642, 644 (1918). Articles shipped in violation of the Act may become subject to state laws otherwise inapplicable. State v. Intoxicating Liquors, 104 Me. 502, 71 Atl. 758 (1908). When an article of food is taken from the interstate package upon receipt and placed in other packages sold within the state, the federal Act does not apply. REG. ANN. 96. On the whole subject of the Act in relation to the "original package" doctrine, see F. I. D. No. 86 (1908).

[5] Weeks v. U. S., 245 U. S. 618, 38 Sup. Ct. 219 (1918).

[6] Section 1 of the Act prohibits the manufacture of misbranded or adulterated food and drugs in the District of Columbia or the territories. Section 2 forbids their being sold or offered for sale in the District of Columbia or the territories. These sections do not apply to the insular possessions. Gonzalez v. People of Porto Rico, *supra,* note 4. But transportation into and from the insular possessions is controlled by the Act, §10.

ney, of misbranded or adulterated foods and drugs.[7] The Supreme Court in the *Hipolite Egg* case[8] decided that this shipment need not be for purposes of ultimate sale and that the law had application though the shipment consist of raw material for use in the preparation of a more complex food product. The substandard food or drug is not permitted to cross the state line even when the shipment is made for the express purpose of removing impurities in the receiving station[9] or for testing for export at such station.[10] Similarly, rotted foodstuffs may not be sent from state to state for tanning or other non-food purposes, unless so denatured as to make their consumption by the public impossible.[11] The excuse that a shipment of drugs constituted but part of medical "services" which were being rendered has similarly failed.[12] The question, however, has remained open whether an individual practitioner violates the law if he sends his patient a drug package with a non-complying label.[13]

BASIS OF VIOLATION UNDER THE BILL

The states, untrammelled by the constitutional limitations of the "commerce" clause, have made the tampering with the food or drug the offense,[14] and have

[7] See ACT, §2. (Manufacture and sale of adulterated or misbranded products are prohibited in the District of Columbia and the territories by §1.) The defendant need not be either a manufacturer, owner, or dealer in the commodity. U. S. v. Buffalo Cold Storage Co., 179 Fed. 865 (W. D. N. Y. 1910). The restriction as to "original unbroken packages" applies only to the receiver of the adulterated or misbranded goods and not to the shipper. See U. S. v. Krumm, 269 Fed. 848, 849 (E. D. Pa. 1921). Under Section 2 the shipment is a violation both in the judicial district from which it is made and to which it is sent. U. S. v. Alaska Consolidated Canneries, 2 F. (2d) 614 (W. D. Wash. 1924). But since the crime is actual shipment, merely contracting or ordering for shipment is not a basis for prosecution. See U. S. v. Hopkins & Co., 199 Fed. 649, 652 (E. D. N. Y. 1912). Nor selling to one who may intend to use a product in interstate commerce. Lewiston Milling Co. v. Cardiff, 266 Fed. 753 (C. C. A. 9th, 1920), *cert.* denied, 254 U. S. 646, 41 Sup. Ct. 15 (1920). But *cf.* U. S. v. Heinle Specialty Co., 175 Fed. 299 (E. D. Pa. 1910). A sale and delivery which necessarily involves interstate transportation may violate the Act though the delivery be to an agent of the foreign receiver within the state. *Cf.* U. S. v. Tucker, 188 Fed. 741 (S. D. Ohio 1911).

[8] 220 U. S. 45, 31 Sup. Ct. 364 (1911). *Accord:* U. S. v. Two Barrels, Dessicated Eggs, 185 Fed. 302 (D. Minn. 1911); U. S. v. 426 Bags, Hog Feed, 276 Fed. 34 (W. D. Mich. 1921).

[9] Union Dairy Co. v. U. S., 250 Fed. 231 (C. C. A. 7th, 1918); U. S. v. Nine Barrels, Butter, 241 Fed. 499 (S. D. N. Y. 1917); see U. S. v. 94 Dozen Bottles, Capon Springs Water, 48 F. (2d) 378, 381 (E. D. Pa. 1930), *aff'd*, 51 F. (2d) 913 (C. C. A. 3d, 1931). Prior to the Hipolite case a manufacturer was allowed to ship to his own agents goods to be properly labeled when finally manufactured. U. S. v. 65 Casks, Liquid Extracts, 170 Fed. 449 (N. D. W. Va. 1909). The Hipolite case involved a shipment to a stranger, but the later decisions broadened the rule. See Philadelphia Pickling Co. v. U. S., 202 Fed. 150, 154 (C. C. A. 3d, 1913). On the importation of food-stuffs for non-food purposes, see Reg. 30. But proper labeling on the part of the receiver prior to seizure by the federal authorities has been held to give the goods immunity. U. S. v. Five Boxes, Asafoetida, 181 Fed. 561 (E. D. Pa. 1910).

[10] Philadelphia Pickling Co. v. U. S., *supra* note 9. Under Section 2 articles are not misbranded or adulterated when intended for export and prepared or packed according to the specifications of the foreign purchaser and in addition do not contain substances in conflict with the foreign law. But note the discussion of this section, *infra* p. 109. It is significant that the bill omits this exemption.

[11] U. S. v. 13 Crates, Frozen Eggs, 208 Fed. 950 (S. D. N. Y. 1913), *aff'd*, 215 Fed. 584 (C. C. A. 2d, 1914); see REG. ANN. 322 (shipment for manufacturing purposes).

[12] Dr. J. L. Stephens Co. v. U. S., 203 Fed. 817 (C. C. A. 6th, 1913).

[13] *Id.* at 819, 824; F. I. D. No. 57 (1907).

[14] For control of tampering, see *e.g.*, ARIZ. REV. CODE (Struckmeyer, 1928) §2702. N. M. STAT. ANN. (1929) §§53-102—53-104; N. Y. CONS. LAWS (Cahill, 1931) c. 1, §198. *Cf.* also PORTO RICO PEN. CODE, §336 (repealed), see PEN. CODE §474; REV. STAT. & CODES (1911) §5928.

analogously supported their control by placing restraints upon retail sale.[15] Likewise in England[16] and Canada[17] legislative attention has been increasingly devoted to checking activities of the selling public other than mere transportation.

To a limited extent only does the bill move in this direction. So far as the adulteration and misbranding of foods, drugs, or even cosmetics (which are now for the first time to be brought within the scope of the law) are concerned, the bill merely repeats the prohibition of their introduction[18] or receipt and delivery[19] in interstate commerce. The bill's novelty lies in the manner of its attempt to control advertising: it scores not the movement of falsely advertised food, drug, or cosmetic packages in interstate commerce but (1) the dissemination of false advertisement by radio broadcast, United States mails, or in interstate commerce generally for the purpose of inducing, directly or indirectly, the purchase of these articles[20] and (2) the dissemination of false advertisement by any means for the purpose of inducing, directly or indirectly, the sale of food, drugs, or cosmetics in interstate commerce.[21] This failure to forbid the actual inundation of interstate commerce by falsely advertised foods, drugs, and cosmetics narrows the scope of the control and the failure to apply the seizure provisions of the law to such articles may rob the bill's false advertising anathema of most important sanctions.[22] Their application would, of course, present the difficult problem of determining how long and over what territory a false advertisement would justify seizure. The other changes which the bill makes in the strictly technical basis of the federal regulation are minor.[23]

[15] The regulation of sale is common. See 1 DUNN, *op. cit. supra* note 2, *passim*. See, *e.g.*, ARIZ. REV. CODE (Struckmeyer, 1928) §2711. For a review of state regulation of the sale of drugs in pharmacies, see Note (1929) 17 CALIF. L. REV. 665.

[16] In England the basis of the offense consists in (1) mixing, staining, powdering, etc., food articles (with intent to sell) so as to render them injurious to health or doing similar acts to drugs so as injuriously to affect quality or potency; (2) selling an article to prejudice of purchaser which is not of nature, substance, or quality demanded by the purchaser; (3) abstracting part of the article so as intentionally to make its effect injurious; (4) wilfully applying certificate or warranty for another or wilfully giving a false label. 18 & 19 GEO. V, c. 31, §§1, 2, 5, 30 (1928).

[17] It is an offense to attach misleading labels or to neglect or refuse to label in accord with the Canadian Act. CAN. REV. STAT. (1927) c. 76 §32. For a summary of recent developments in the English legislation, see (1932) 96 JUST. P. 88.

[18] BILL, §17 (a) (1). The use of the term "introduction" does not add anything to the existing law. *Cf.* the use of the same term in the Act, §2. "Interstate commerce" under the bill is a term of art and includes foreign commerce. *Cf.* BILL, §2 (e) (1). Interstate commerce is also defined as "commerce and manufacture within the District of Columbia or the Canal Zone or within any territory not organized with a legislative body." *Id.* §2 (e) (2). This part of the definition is anomalous. Commerce between the District of Columbia and other states is not expressly included in Section 2 (e) (1) and the apparent result is that to violate the new Act in the District of Columbia and the insular possessions one must be shown to have "introduced" the food or drug article into both commerce and manufacture.

[19] BILL, §17 (a) (2).

[20] BILL, §17 (a) (3). The purchase need not be made through a channel of interstate commerce.

[21] BILL, §17 (a) (4). Questions may well arise as to whether the "sale" covered by this section means one which must necessarily result in or induce a transportation of the article across state boundaries. That such must be its meaning is clear when one considers that all "sales" are legally localized within particular states.

[22] See *infra* p. 111. To a limited extent, the bill may prohibit such shipment where the extra-package publicity is made in media technically classed under "labeling." See *infra* p. 86.

[23] Section 17 (a) (5) forbids the introduction into interstate commerce of foods, drugs, and cosmetics if

MISBRANDING UNDER THE ACT

The differences which the proposed legislation introduces in the control of misbranding can be revealed only by a close comparison of Sections 6, 7 and 8 of the bill with Section 8 of the Act and the decisions and regulations interpreting and enforcing the latter. For in both the bill and the Act "misbranded" is largely a word of art. An analysis of Section 8 of the Act shows three discrete types of "misbranding":

(1) Where the label is affirmatively false or misleading;[24]

(2) Where the label fails to state the quantity or proportion of ten enumerated drugs, their derivatives, or compounds,[25] or in the case of packaged goods, omits conspicuous marks of weight, measure or numerical count;[26]

(3) Where the product is an imitation of, or is offered for sale under, the name of another article.[27]

The "label" includes any legend, design, or pictorial device on the package itself, pasters or tags, pamphlets, circulars, etc., affixed to the outside of the package,[28] and pamphlets and circulars enclosed within the package in the case of therapeutic misrepresentations under the Sherley Amendment.[29] Perhaps also misstatements as to

the manufacturer, processor, or packer does not hold a valid permit when required. See *infra* p. 105 Section 17 (a) (6) penalizes a refusal to permit access to or copying of certain records of interstate shipment, by carriers subject to the Interstate Commerce Act. *Cf.* BILL, §14. For a similar duty upon carriers under a state food and drug law, *cf.* ILL. REV. STAT. (Cahill, 1929) c. 56b, §3. Many states have provisions which make it a crime to hinder, obstruct, or interfere with food and drug inspection. See, *e.g.* 2 IND. STAT. ANN. (Burns, 1926) §8230; ILL. REV. STAT. (Cahill, 1929) c. 56b, §3. See also CAN. REV. STAT. (1927) c. 76, §27. For a provision specifically exempting common carriers who innocently receive adulterated or misbranded articles of food in the ordinary course of business, see IOWA CODE (1931) §3049.

[24] The statement, design, or device must be misleading or false regarding the article contained in the package to which the label is affixed, the ingredients or substances contained therein, or regarding territorial source. Section 8 is so worded as to exclude statements which are misleading as to other articles in competition with that in the labeled package.

[25] The drugs which must be mentioned are alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilid, or any derivative or preparation of such substances. ACT, §8 (Drugs, 2). Food products must be labeled and indicate the presence of these substances with the exception of alcohol. *Id.* (Food, 2). The presence of alcohol must be indicated even in a preparation used only for inhalation. The Congressional intent in forcing the disclosure was not only to reduce the consumption of liquor and prevent the innocent formation of the habit of liquor drinking but also to inform the consumer of the presence of the enumerated drugs. U. S. v. 11 Cartons, Drug, etc., 59 F. (2d) 446 (D. Md. 1932). Not only must the derivative be indicated on the label but also the name of the specified drug of which it is a derivative. U. S. v. Antikamnia Chemical Co., 231 U. S. 654, 34 Sup. Ct. 222 (1913). *Cf.* also Reg. 24 (Substances required to be stated on label). As to when the term "Poison" must appear on the label, see the Caustic Poison Act, 44 STAT. 1406 (1927), 15 U. S. C. A. §§402, 403 (Supp. 1933).

[26] *Cf.* Reg. 26. This provision of the law was added by the Gould Amendment, 37 STAT. 732 (1913), 21 U. S. C. A. §10 (3), in turn amended by the Kenyon Amendment defining its application to wrapped meats. 41 STAT. 271 (1919), 21 U. S. C. A. §10. The Bill deals with the wrapped meat problem by including such articles in the term "in package form." *Cf.* BILL, §2 (k). The statute expressly permits "reasonable variations" as to weights and counts. This permission does not render the paragraph unconstitutional as setting up too "indefinite" a standard in a criminal statute. U. S. v. Shreveport Grain & Elevator Co., 287 U. S. 77, 53 Sup. Ct. 42 (1932). *Cf.* U. S. v. Rigney & Co., 220 Fed. 734 (E. D. N. Y. 1915).

[27] For a violation of (3) no deceptive label is necessary. The offer may be made by the oral representations of a salesman. Weeks v. U. S., *supra* note 5.

[28] Reg. 14.

[29] 37 STAT. 416 (1912), 21 U. S. C. A. §10 (Drugs, 3). The Congressional power validly extends to

non-therapeutic effects when made in the circulars are prohibited in the rare case in which the label itself refers to such representations and incorporates them by the reference.[30] The federal label clearly includes not only that on the outer carton, but also that physically attached to the retail package.[31]

Two statutory exceptions are made: (a) mixtures or compounds known as articles of food and sold under their own distinctive names and which neither contain added poisonous or deleterious ingredients, nor violate (3) above are not to be deemed misbranded where the distinctive name is accompanied with a statement of the place of manufacture;[32] (b) compounds, imitations or blends are not misbranded if plainly tagged or labeled "compound," "imitation," or "blend" respectively. The "blend" must be a mixture of like substances.[33]

The Act's protection is not narrow. Thus, cornstarch may be botanically a fruit but its presence cannot make an article "fruit"-flavored.[34] The test of the label's truth is not chemical, botanical, or scientific accuracy[35] but rather the generally understood signification of the label as a concatenated whole[36] to persons of ordinary intelligence, familiar with the product, and conversant with the English language.[37] Similarly, the fact that the term used in the label correctly characterizes the product to people aware of a special trade nomenclature or custom does not matter[38] unless such nomenclature or custom be so widespread as to negate the possibility of deception.[39] But an otherwise truthfully labeled product must, however, meet the requirements of a fully developed trade connotation.[40]

The label may not misstate the nature or the identity of the article,[41] or imply that

circulars contained within the package. Seven Cases, Eckman's Alterative v. U. S., 239 U. S. 510, 36 Sup. Ct. 190 (1916). *Contra:* (prior to the amendment) U. S. v. Am. Druggists' Syndicate, 186 Fed. 387 (C. C. E. D. N. Y. 1911). The Sherley Amendment has been held to include under "label" booklets enclosed within the carton only where false and fraudulent representations are concerned. U. S. v. 17 Bottles, etc., 55 F. (2d) 264 (D. Md. 1932).

[30] Reg. 14.

[31] McDermott v. Wisconsin, *supra* note 4 at 131, 33 Sup. Ct. at 434. But an invoice is not a label under the Act. Hall-Baker Grain Co. v. U. S., 198 Fed. 614 (C. C. A. 8th, 1912).

[32] *Cf.* Reg. 18.

[33] *Cf.* Reg. 19.

[34] U. S. v. 150 Cases, Fruit Puddine, 211 Fed. 360 (D. Mass. 1914).

[35] U. S. v. Scanlon, 180 Fed. 485 (N. D. Ohio, 1908); U. S. v. 75 Boxes, Alleged Pepper, 198 Fed. 934 (D. N. J. 1912). In considering whether a food product is misbranded, the courts will turn to the designations given in dictionaries, trade journals, the trade, market reports, newspapers and official publications regarding food. See U. S. v. One Car Load, Corno Horse & Mule Feed, 188 Fed. 453, 463 (M. D. Ala. 1911).

[36] See Newton Tea & Spice Co. v. U. S. 288 Fed. 475, 479 (C. C. A. 6th, 1923).

[37] See U. S. v. 75 Boxes, Alleged Pepper, *supra* note 35, at 935; U. S. v. One Car Load, Corno Horse & Mule Feed, *supra* note 35, at 462.

[38] Libby, McNeill & Libby v. U. S., 210 Fed. 148 (C. C. A. 4th, 1913); Brina v. U. S., 179 Fed. 373 (C. C. A. 2d, 1910). But the federal Act does not interfere with the contracts of parties for shipment of products described under trade names. Walker v. Gateway Milling Co., 121 Va. 217, 92 S. E. 826 (1917).

[39] Von Bremen v. U. S., 192 Fed. 904 (C. C. A. 2d, 1912); see Brina v. U. S., *supra* note 38; *cf.* U. S. v. 30 Cases, Grenadine Syrup, 199 Fed. 932 (D. Mass. 1912). *Cf.* (1933) 31 MICH. L. REV. 804, 816. It has been suggested that under the Act, no commercial practice could legally establish a novel system of liquid and weight measures. U. S. v. Rigney & Co., *supra* note 26, at 736.

[40] U. S. v. 75 Boxes, Alleged Pepper, *supra* note 35.

[41] U. S. v. 95 Barrels, Vinegar, 265 U. S. 438, 44 Sup. Ct. 529 (1924); U. S. v. Five Cases, Champagne, 205 Fed. 817 (N. D. N. Y. 1913) (even though the name of the article represented does not appear on

it contains ingredients actually absent.[42] Michigan apples cannot be presented as coming from Arkansas trees;[43] the Act protects geographical terms[44] unless the terms have become so generic as to indicate types, classes, or styles rather than places of origin or manufacture.[45] The product must also satisfy its package's representations as to strength, quality, grade or purity.[46]

Nor has the immunity of the statutory exceptions been altogether easy to gain, nor when gained, has such immunity proved absolute. The courts have held that to give a proprietary food product a distinctive name which suggests ingredients which are in fact absent is to employ not "its own distinctive name," distinguishing it from other compounds, but rather the name of a different compound possessing those ingredients and hence is deceptive.[47] And merely utilizing the words "compound" or "blend" does not exempt wares from other statutory inhibitions,[48] especially where the word "compound" is used as an adjective suggestive of "added strength" rather than indicative of an internal combination of substances.[49]

The misbranding of drugs forms a separate topic. In 1911 the Supreme Court in *United States v. Johnson*[50] held the term "misbranded" to apply only to false state-

the label); Washburn & Co. v. U. S., 224 Fed. 395 (C. C. A. 1st, 1915); Libby, McNeill & Libby, *supra* note 38. *Cf.* Johnson, *The Case of "Courts vs. Bureaucrats"* (Nov. 1931) STANDARD REMEDIES, 2, 4.

[42] Newton Tea & Spice Co. v. U. S., *supra* note 36.

[43] U. S. v. 100 Cases, Tepee Apples, 179 Fed. 985 (W. D. Mo. 1908).

[44] U. S. v. 267 Boxes, Macaroni, 225 Fed. 79 (W. D. Pa. 1915) ("mfg. in U. S." printed in small letters where all wording in Italian and name of Italian city used); Schraubstadter v. U. S., 199 Fed. 568 (C. C. A. 9th, 1912) (court considers "dress" of the package). The problem of deception when a local American city has the same name as a foreign country is often a close one. *Cf.* U. S. v. Finlayson, N. J. No. 2914 (S. D. N. Y. 1913); U. S. v. Schurman, 177 Fed. 581 (W. D. Mich. 1910).

[45] U. S. v. Thomson & Taylor Spice Co., 198 Fed. 565 (N. D. Ill. 1912), with which *cf.* F. I. D. No. 91 (1908); U. S. v. 36 Bottles, London Dry Gin, 205 Fed. 111 (E. D. Pa. 1913), *rev'd* on other grounds, 210 Fed. 271 (C. C. A. 3d, 1914). In 1910, F. I. D. No. 115 restricted the term "Rocky Ford" melon to melons of a particular locality; F. I. D. No. 166 reversed that decision because by 1916 the term had become sufficiently generic. On foreign names, see Reg. 17. For the problem raised by the use of the term "whiskey," see F. I. D. No. 127 (1910); TAFT, WHAT IS THE MEANING OF THE TERM "WHISKEY" (Govt. Printing Office, 1909).

[46] Wood Mfg. Co. v. U. S., 286 Fed. 84 (C. C. A. 7th, 1923); U. S. v. 200 Cases, Canned Salmon, 289 Fed. 157 (S. D. Tex. 1923).

[47] U. S. v. Coca Cola Co., 241 U. S. 265, 36 Sup. Ct. 573 (1916), (1916) 30 HARV. L. REV. 193. But the proprietary name gives protection where it has achieved a secondary significance descriptive of a product known to be destitute of ingredients indicated by its primary meaning. See U. S. v. Coca Cola, *supra* at 288, 36 Sup. Ct. at 581; *Cf.* U. S. v. 150 Cases, Fruit Puddine, *supra* note 34. The proviso regarding distinctive names does not apply where the charge of misbranding is directed not against the name but against false statements on the label. Newton Tea & Spice Co. v. U. S., *supra* note 36. The fact that a proprietary name is a trade-mark may tend to a more favorable consideration. See U. S. v. 23 7/12 Dozen Bottles, etc., 44 F. (2d) 831, 838 (D. Conn. 1930).

[48] U. S. v. Schider, 246 U. S. 519, 38 Sup. Ct. 369 (1918) ("Compound Ess Grape" insufficient to show product an imitation); Henning & Co. v. U. S., 193 Fed. 52 (C. C. A. 5th, 1912) ("Compound Tomato Catsup" misbranded when product had pumpkin); U. S. v. Ten Barrels, Vinegar, 186 Fed. 399 (E.D. Wis. 1911) ("Blend of Apple Cider and Distilled Vinegar" misbranded when product not apple cider vinegar and distilled vinegar). Where product is an imitation, the law is mandatory that word "imitation" appear on label. "Artificial" does not suffice. Reg. Ann. 369.

[49] Frank v. U. S., 192 Fed. 864 (C. C. A. 6th, 1911); U. S. v. Weeks, 225 Fed. 1017 (S. D. N. Y. 1912).

[50] 221 U. S. 488, 31 Sup. Ct. 627 (1911). Accord: U. S. v. Hygiene Health Food Co., N. J. 1265 (N. D. Cal. 1911).

ments as to the identity or quality of foods and drugs and not to declarations of therapeutic or curative effects. The decision was contrary to departmental interpretation and the probable Congressional intent.[51] To stop the serious gap created by the decision, Congress passed the Sherley Amendment[52] which forbids "false and fraudulent" representations as to the therapeutic effects of drugs. For this type of misbranding, therefore, actual intent to deceive is a condition of the statutory offense, an intent, however, which may be inferred from the circumstances.[53] Bracketing the medical hocus as a quotation from actually received testimonials has been held but an indirect and invalid method of deception.[54] The law has taken note also of advance in medical knowledge and experience so that a "cure" or "remedy" which will pass judicial muster in one decade may fail in the next.[55]

The consumer therefore has at the present time a degree of protection from misbranding. Consider now the other side of the picture. The law does not apply to advertising matter in media physically detached from the package,[56] and by a recent decision even the pamphlets enclosed within the package can legally be both false and misleading.[57] A bottle of orange colored sugar water or a simple cereal food may be correctly labeled. The law may be meticulously observed; yet billboards, newspapers, magazines, and radio may endow them with most valuable ingredients and herald the medicinal virtues of such inert products with blatant charlatanry.[58] Since interstate shipment is the crime, apparently nothing (as far as the federal Act is concerned) prevents a shipper from sending products across the state boundary line

[51] See the argument for the Government in U. S. v. Johnson, *supra* note 50, at 490.

[52] 37 STAT. 416 (1912); 21 U. S. C. A. §10 (Drugs, 3).

[53] Dr. J. H. McLean Medicine Co. v. U. S., 253 Fed. 694 (C. C. A. 8th, 1918); Bradley v. U. S. 264 Fed. 79 (C. C. A. 5th, 1920); Chichester Chemical Co. v. U. S., 49 F. (2d) 516 (App. D. C. 1931); See Seven Cases, Eckman's Alterative v. U. S., *supra* note 29, at 517, 36 Sup. Ct. at 193. Since falsity of therapeutic representations is an element of the violation, expert testimony on that fact is admissible. Hall v. U. S., 267 Fed. 795 (C. C. A. 5th, 1920). As fraudulent intent is an element, self-serving letters are admitted, Chichester Chemical Co. v. U. S., *supra*, and testimonials received by the defendant are admissible to show his good faith regardless of proof of their execution or of the truth of their subject matter. See Dr. J. H. McLean Medicine Co. v. U. S., *supra*, at 697. On refund guaranties connected with therapeutic representations, see Reg. Ann. 21.

[54] U. S. v. Fulton Co., 33 F. (2d) 506 (C. C. A. 9th, 1929).

[55] *Cf.* Aycock v. O'Brien, 28 F. (2d) 817 (C. C. A. 9th, 1928), with U. S. v. Tuberclecide Co., 252 Fed. 938 (S. D. Cal. 1916).

[56] See Alsberg, *Ten Years of Food and Drugs Enforcement*, REP. SEC. AGR. (1917) 212; *Ballyhoo or Truth?* (Dept. Agr., Aug. 28, 1933). Showing in the case of Lydia Pinkham Vegetable Compound the shift of therapeutic claims away from the label, see LEECH, THE SAFEGUARDING OF DRUGS IN CHEMISTRY IN MEDICINE (ed. Stieghty, 1928) 395, 400. For an illustration of the inability to reach products advertised through non-package media, see CHASE & SCHLINK, YOUR MONEY'S WORTH (1928) 134. Patent medicines are sold to the public primarily by virtue of non-package advertising, CHASE & SCHLINK, *op. cit. supra* at 123. Similarly the Packers & Stockyards Act, 42 STAT. 159 (1921), 7 U. S. C. A. §181, does not reach such advertising matter. The statutory crime of using the mails to defraud, FED. CRIM. CODE §215, 35 STAT. 1130 (1909), 18 U. S. C. A. §338, and the power of the Post Office Department to issue fraud orders, 17 STAT. 322, 323 (1872), 39 U. S. C. A. §§259, 732, are restricted to mail circulars.

[57] U. S. v. 17 Bottles, etc., *supra* note 29.

[58] See (1931) 97 AM. MED. ASSN. J. 32; Cramp, *Truth in Advertising Drug Products* (1920) 10 AM. J. PUB. HEALTH 783. For an illustration, see *Electro-vita-Weak Lime Water Plus Hokum* (1932) 98 AM. MED. ASSN. J. 337.

without a label and then affixing thereon one most outrageously deceptive.[59] The only exception is the inferred requirement of a label where the article contains one of the ten enumerated drugs. With a few exceptions, labels when present must mention the presence of only these ten drugs and are immune from any other rules as to affirmative disclosure.[60] Other poisons and all kinds of habit-forming drugs may be in the article without disclosure being required.[61] Moreover, except as to the ten drugs[62] the law is silent as to the proportion of ingredients,[63] so that a package labeled "Peroxide Cream" may have peroxide in a most minute and negligible quantity.[64] The statutory exceptions as to blends and distinctive names have permitted the use of labels not completely truthful.[65] The container may be shaped, colored or dressed in any way desired without liability;[66] yet more deception as to quantity, quality, size or contents may result than from any possible label. In the field of therapeutic representations, a fine line between "remedy" and "cure" has been drawn although as often as not the gullible purchaser has been deceived in both instances;[67] and the label may contain the most puffed and ridiculous statements.[68]

[59] Such is apparently the legal effect of Weeks v. U. S., *supra* note 5, save when the product is offered for sale under the name, or as an imitation of, another article. *Cf.* Reg. 15 (When Label Required).

[60] See Savage v. Jones, *supra* note 4, at 531, 32 Sup. Ct. at 725; Newton Tea & Spice Co. v. U. S., *supra* note 36, at 480. For the list of drugs, see note 25, *supra*.

[61] See REP. SEC. AGR. (1920) 52; CHASE & SCHLINK, *op. cit. supra* note 56, at 47. For the failure of the Act to reach a new poison, see *Thallium Poisoning* (1932) 98 AM. MED. ASSN. J. 406.

[62] See U. S. v. 65 Casks, Liquid Extracts, *supra* note 9; *cf.* Reg. 24 and 25 and the provisions of the Act, *supra* note 25.

[63] *In re* Wilson, 168 Fed. 566 (C. C. D. R. I. 1909); U. S. v. Boeckmann, 176 Fed. 382 (C. C. E. D. N. Y. 1910); *cf.* Lexington Mill & Elevator Co. v. U. S., 202 Fed. 615 (C. C. A. 8th, 1913), *aff'd* on other points, 232 U. S. 399, 34 Sup. Ct. 337 (1914). On statements as to weight, measures and counts in packaged goods, *cf.* Reg. 26 and U. S. v. Shreveport Grain & Elevator Co., *supra* note 26.

[64] U. S. v. Am. Druggists' Syndicate, *supra* note 29.

[65] Illustrative are U. S. v. 68 Cases, Syrup, 172 Fed. 781 (E. D. Ill. 1909) ("Blended Syrup—made by X, Blender of Fancy Maple Syrup and Maple Sugar" not misleading though no maple syrup); U. S. v. Blanke Tea & Coffee Co., N. J. No. 2797 (E. D. Mo. 1913) ("Mojav Coffee . . . A special blend of good drinking coffee" not misleading as indicating blend of Mocha and Java coffees though product almost entirely of Santos coffee); U. S. v. Ten Cases, Bred Spred, 49 F. (2d) 87 (C. C. A. 8th, 1931) (Strawberry "Bred Spred" not indicative of strawberry jam). An averment that a defendant branded an article with a label correctly describing it but intending the public or purchasers to understand something else fails to state a violation. Nave-McCord Mercantile Co. v. U. S., 182 Fed. 46 (C. C. A. 8th, 1910).

[66] REP. SEC. AGR. (1920) 52; YEARBOOK, DEPT. AGR. (1928) 405; ROGERS, GOOD WILL, TRADE-MARKS AND UNFAIR TRADING (1919) 194. For the protection given by the Federal Trade Commission in instances of false packaging, see PUBLIC REGULATION OF COMPETITIVE PRACTICES (Nat. Ind. Conf. Bd., 1929) 147-149.

[67] *Cf.* U. S. v. Natura Co., 250 Fed. 925 (N. D. Cal. 1917); Simpson v. U. S., 241 Fed. 841 (C. C. A. 6th, 1917). A similar disregard of the effect on the consumer has resulted from a too strict application of the *ejusdem generis* doctrine to therapeutic representations. *Cf.* Chichester Chemical Co. v. U. S., *supra* note 53.

[68] Some courts seem entirely too content with a "commercial" standard of truth, piously hoping that the purchaser will not be so gullible as to be deceived by the depicted panaceas. "This label is as close an adherence to the truth as is customary in commercial labels, and speaks the truth as nearly as would be expected of any advertiser of a commercial product . . . [many of the claims] are so extravagant as to justify the characterization of being ridiculous. No trial judge is in a position to pit his judgment of the benefit to the seller of certain commercial practices against the judgment of commercial men." Dickinson, J., in U. S. v. 94 Dozen Bottles, Capon Spring Water, *supra* note 9, at 380, 382. On such puffed advertising in even reputable medical journals, see HARDING, FADS, FRAUDS, AND PHYSICIANS (1930) c. VII.

One ingenious bottling concern lauded to the skies the therapeutic values of its spring water and successfully defended its label on the ground that *any* water if drunk liberally had these same values![69]

Unfortunately, too, because of the law's definition of a "drug" as something used for disease,[70] all kinds of cosmetics, powders, and depilatories may be palmed off on an unsuspecting public and, not being foods or drugs, completely escape both the misbranding and the adulteration provisions, unless their promoters, unguided by counsel, inadvertently place therapeutic statements as to "disease" on the label.[71] Therapeutic mechanical devices, ray machines, and "health" lamps are likewise not reached by the Act.[72] And since obesity is not strictly a disease, the market has been flooded with pills, salts, salves, and ointments hailed with most pretentious claims as to reduction of weight and having the most dubious, if not injurious, results.[73]

MISBRANDING UNDER THE BILL

The bill bravely attempts to remedy all the defects indicated, and the result is an exceptionally comprehensive and complete control. Its remedial effort pushes along various directions—by its enactment a host of new articles would be by a legislative swoop brought within the Act, new affirmative duties of truth telling would be imposed in addition to strengthening of older prohibitions, and the label would cease to be the federal fulcrum of activity. Some of the changes which at first glance seem radical departures will be seen on inspection to be but clarifications of the present

[69] U. S. v. 94 Dozen Bottles, Capon Spring Water, *supra* note 9.

[70] Section 6 of the Act provides that the term drug includes all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary and any substance "intended to be used for the cure, mitigation, or prevention of disease of either man or other animals." An inhalant may be a drug under the Act. United States v. 11 Cartons, Drug, etc., *supra* note 25. Most state statutes repeat the federal definition. See 1 DUNN, *op. cit. supra* note 2, *passim*. But *cf.* OKLA. COMP. STAT. ANN. (Harlow, 1931) §4540 ("care, protection or prevention of disease"). The Canadian and English definitions are similar to that in the federal Act. *Cf.* REV. STAT. CAN. (1927) c. 76, §2 (c); 18 & 19 GEO. V, c. 31, §34. On what is a "proprietary or patent medicine" under state laws, see Ferguson v. Arthur, 117 U. S. 482, 6 Sup. Ct. 861 (1886); State v. Jewett Market Co., 209 Iowa 567, 228 N. W. 288 (1929); Note (1932) 76 A. L. R. 1207. For a review of the present deficiencies of the Act in regard to drugs, see Cramp, *Patent Medicines and the Law*, AM. MERCURY, Nov. 1933.

[71] REP. SEC. AGR. (1913) 18; See Harding, *The Consumer and the Medicine Cabinet*, J. HOME ECON. (July, 1930) 558, 560; KALLETT & SCHLINK, 100,000,000 GUINEA PIGS (1933) c. V; *Beauty at Cost* (Dept. Agr., Aug. 28, 1933). The Federal Trade Commission does some work in regard to misleading advertisements of cosmetics. See PUBLIC REGULATION OF COMPETITIVE PRACTICES, *supra* note 66, at 102-127. For special problems arising in connection with antiseptics, see FAKE ANTISEPTICS AND THE LAW (F. and D. Adm., 1930); (1929) 93 AM. MED. ASSN. J. 1225; Note also the particular mention of antiseptics in the statutes cited *infra* note 79. KALLETT & SCHLINK, *op. cit. supra*, c. VI. Therapeutic statements on the label as to disease would make the cosmetic automatically a legal drug (see Harding, *supra*), just as, when curative claims are advanced as to water (classified as a food under the Act), water may be proceeded against as a drug. Bradley v. U. S., *supra* note 53; Goodwin v. U. S., 2 F. (2d) 200 (C. C. A. 6th, 1924). Cigars and cigarettes are also not within the Act despite frequent semi-therapeutic advertisements. For a criticism of such advertisements, see (1930) 94 AM. MED. ASSN. J. 810. But once a preparation is declared a drug, it is fully subject to the Act's requirements for drugs even though *prima facie* such requirements seem inapropos. U. S. v. 11 Cartons, Drug, etc., *supra* note 25.

[72] REP. SEC. AGR. (1930) 56; *Contraptions or Cures* (Dept. Agr., Aug. 28, 1933).

[73] REP. SEC. AGR. (1920) 52; see Harding, *What the Food and Drug Administration Does* (1930) 15 SCIENTIFIC MONTHLY 522, 524. For a striking illustration of dangerous obesity "cures," see (1931) 97 AM. MED. ASSN. J. 1555.

state of the law; many are wholly new. The description of the bill's effect is further complicated by the fact that to some extent, at least, the misbranding features of the bill have been employed with a view toward stopping certain types of adulteration.[74]

New articles are included. Cosmetics would appear for the first time in a federal regulatory statute.[75] As defined, it includes all substances and preparations intended for cleansing, or altering the appearance of, or promoting the attractiveness of, the person.[76] The definition seems broad, yet comparison with the definition of cosmetics made in the Retail Code[77] under the National Recovery Act would seem to indicate that the bill's definition may not cover many lotions, soaps, and powders used for "refreshing" the person. It is not impossible, however, that these as well as many cosmetic preparations clearly included within the bill are covered by the bill's broader definition of a drug.[78] It is interesting to note that despite the widespread use of cosmetics only some six states, Hawaii, and the District of Columbia appear to have food and drug statutes subjecting them to control.[79] In each case hitherto the method of subjection has been by considering the cosmetic as a technical "drug."[80] The effect of the bill's not placing cosmetics similarly in the drug class will be the subject of later consideration in this article.[81]

But drug is now to include "all substances and preparations, other than food. . . . intended to affect the structure or any function of the body of man or other animals."[82] In other words, the anti-obesity hokums and the nostrums advertised for

[74] *Cf.* BILL, §§7 (d), 7 (e), 8 (g).

[75] For the extent to which the present bill controls cosmetics, see *infra*, p. 105. The Associated Manufacturers of Toilet Articles have objected to the inclusion of cosmetics with drugs on the ground that their products would thereby be brought within the purview of state pharmacy laws. See Summary of Conference with Drug Trade Representatives, April 27, 1933, at 3.

[76] BILL, §2 (c).

[77] Schedule "A," Section 1 (5), reads "Cosmetics and Toilet Preparations—The term cosmetics and the term toilet preparations as used herein shall mean toilet articles and perfumes, toilet waters, face powders, face creams, rouges, shaving creams, dentifrices, soaps and similar substances and preparations designed and intended for application to the person for the purpose of cleansing, improving the appearance of, refreshing or preserving the person." Contrast with this the restricted character of "cosmetics" as used in the Tariff Act of 1922, 42 STAT. 858 (1922), 19 U. S. C. A. §121, sched. 1, par. 62.

[78] *Cf.* BILL, §2 (b) (3).

[79] CAL. PEN. CODE (Deering, 1931) §383; IND. ANN. STAT. (Burns, 1926) §2655; WIS. STAT. (1931) §352.01; N. D. COMP. LAWS ANN. (Supp. 1925) 2889b 4. ("The term 'drug' as used in this act shall include all medicine for internal or external use, antiseptics, disinfectants, washes, perfumes, and cosmetics."); OHIO GEN. CODE (Page, 1931) §5775 ("The term 'drug' as used in this chapter, includes all medicines for internal or external use or inhalation, antiseptics, disinfectants and cosmetics"); W. VA. CODE (1932) c. 16, art. 7, §1 (Drug "shall include all medicines for internal or external use, antiseptics, disinfectants and cosmetics"); HAWAII REV. LAWS (1925) c. 76, §993 ("The term 'drug' as used in this chapter shall include all drugs, medicines, or medical preparations for external or internal use, antiseptics, antiseptic dressings, disinfectants and cosmetics"); D. C. CODE (1929) tit. 20, §1222 ("The term 'drug' as used in this act, shall include all medicines, for external or internal use, antiseptics, disinfectants and cosmetics").

[80] *Cf.* the statutes cited *supra* note 79.

[81] See *infra*, p. 118.

[82] BILL, §2 (b). The bill's definition of drug changes "medicines and preparations" in the U. S. P. or N. F. [Act, §6] to "substances and preparations." The bill's definition also includes substances and preparations in supplements to the Pharmacopoeia and Formulary official at the time of the introduction of the drug into interstate commerce. On the validity of this indirect delegation of power to private

general health rather than strictly disease purposes are to lose their immunity. The exclusion of food from the definition seems necessary to prevent every article of food coming within the category of the new "drug." On the other hand, the exclusion might prove to be a most dangerous loophole as by cleverly advertising as foods, the anti-obesity pills, yeasts, and tablets may be given new leases of legal longevity. This result could have been avoided by having the purpose for which a product was manufactured, dispersed, sold, or offered for sale determinative of its character.[83]

Finally, the quacks and the fakes who have preyed upon sufferers from such diseases and ailments as rectal cancer, goitre, asthma, diabetes, etc., by selling them fake belts, machines, straighteners, exercisers, and similar devices would find their articles of trade under the federal law. Under the provisions of Section 2 of the bill, the term "drug" includes two types of devices: those intended for use in the cure, mitigation, treatment, or prevention of disease,[84] and those intended to affect the structure or function of the body.[85] Devices for cleansing, altering the appearance of, or promoting the attractiveness of the person are apparently not included, but since the fake contraptions will frequently accomplish the beautification objects by affecting structural or functional changes, many of them would be within the new Act's condemnation.

Sections 6, 7 and 8 of the bill set forth the new commandments on the subject of misbranding. Section 6 is devoted to misbranding in general. Under its provisions, a food, drug, or cosmetic is to be deemed misbranded:

(a) if its "labeling is in any particular false, or by ambiguity or inference creates a misleading impression regarding any food, drug, or cosmetic";[86]

(b) if in the case of packaged goods, its label does not contain the name and place of business of the manufacturer, packer, seller, or distributor, as the case may be, together with an accurate statement of weight, measure, or numerical count as prescribed by regulations of the Secretary of Agriculture;[87]

groups of citizens, see Note (1932) 32 COL. L. REV. 80. For a history of pharmacopoeias, see LA WALL, FOUR THOUSAND YEARS OF PHARMACY (1927). The definition adds also the word "treatment."

The definition of food as given in the bill in Section 2 (a) expressly includes substances and preparations entering into the composition of food, drink, confectionery or condiment. *Cf.* ACT, §6. The change seems only to read into the law the result of the Hipolite Egg case, *supra* note 8. The bill's definition seems modeled on the English law. *Cf.* 18 and 19 GEO. V, c. 31, §34. As to what are "foods" within the statutory definition, see Note (1922) 17 A. L. R. 1282. Tobacco is probably not within the scope of the bill. *Cf.* State v. Ohmer, 34 Mo. App. 124 (1889), and note 71, *supra.*

[83] *Cf.* DEL. REV. CODE (1915) c. 100, §80. With the exception indicated in the text, the definition of foods, drugs, and cosmetics are not to be mutually exclusive. BILL, §2(c). Neither are they exclusive under the present Act. *Cf.* U. S. v. 94 Dozen Bottles, Capon Spring Water, *supra* note 9.

[84] BILL, §2(b) (2).

[85] *Id.* §2(b) (3).

[86] BILL, §6(a). *Cf.* Ill. "Rules for Labeling. §7. Deceitful and suggestive names and designs shall not be used. No design presenting a superior ingredient, its source or a process of its manufacture, shall appear on the label unless the inferior ingredients are likewise so represented in an equally prominent manner."

[87] BILL, §6(b). The authority to make reasonable variations as to weight and count, and exemptions as to small packages is repeated. *Id.* The exemption as to small packages when permitted by the Secretary of Agriculture does not extend to small packages of drugs. *Id.* The Secretary may exempt classes of

(c) if data required on the label to avoid adulteration or misbranding under any of the provisions of the bill are not so conspicuously placed as to be easily seen and so phrased as to be readily intelligible to the purchaser or user under customary conditions of purchase and use.[88]

Section 6 (a) must be read in conjunction with the definition of "labeling"[89] given earlier in the bill which as defined includes both labels "and other written, printed, and graphic matter, in any form whatever accompanying any food, drug, or cosmetic." Such a conjunctive reading indicates that the Sherley Amendment in respect to circulars and pamphlets within the package is herewith extended to all articles covered by the bill—foods and cosmetics as well as drugs—and to all types of misrepresentation. The present clause is unambiguous: physical detachment from the package is not to confer a privilege to dupe the consumer.

An interesting question arises as to whether subsection (b) has not gone even beyond the terms of the Sherley Amendment. That amendment succeeded in reaching the detached circulars by providing that the drug article was to be misbranded if its package should "bear *or contain*" the false and fraudulent statements. The definition of "labeling" as given in the bill eschews this terminology; under its broad language the law now is to affect all literature which in any way may be deemed as "accompanying"[90] the interstate package. In view of the bill's definition of "advertisement"[91] placed in juxtaposition to that labeling and expressly excluding "labeling," evidently representations in media remote from the package are not included. Not so patently, however, is "labeling" confined to the world within the package, and it is not unlikely that under the technical definition of "labeling" will come such methods of representation to the public as placards, signs, and showcards placed in proximity with the package and possibly also representations affixed to racks, trays, and showcases in which the packages are placed for display on retail sale.

canned goods from the requirement of noting the numerical count or weight during transportation, in accordance with trade practice, to establishments for labeling. Such transportation would not otherwise be permitted. *Cf.* notes 9, 10, *supra.* Under the present Act, §6, the Gould Amendment as to weight and numerical count applies only to packaged foods. The bill extends the provision to packaged drugs and cosmetics.

Under the wording of Section 6(b) of the bill, the requirement for disclosure of name and place of business may be satisfied by giving those of the manufacturer, packer, seller, *or* distributor. *Semble*, where an article is manufactured by A and sold by B, the label need not have both the name of A and B. *Cf.* ILL. REV. STAT. (Cahill, 1933) c. 56b, §9 (4). Accordingly, the provision seems easy of evasion by the use of dummy distributing companies. It is interesting to note that comparable state statutes insist upon "the name of the *real* manufacturer, jobber, etc." *Cf.* CAL. GEN. LAWS (1931), Act 57, No. 6(5); NEV. COMP. LAWS (Hillyer, 1924) §6188 (5); N. D. COMP. LAW (Supp. 1926) §2289b 6; 2 OKLA. COMP. STAT. ANN. (Bunn 1921) c. 79, §8838. These statutes expressly require the name and place to be stated in clear and distinct English words in legible type. Canada deems a packaged food or drug misbranded if the label bears the name of an individual or of a company claimed to be the manufacturer or producer of the article which individual or company is fictitious or nonexistent. CAN. ORD. IN C. (1928) §7. The only requirement in the present Act for disclosure of source is that of the place or manufacturer or production in the exceptional case of mixtures and compounds seeking the statutory "distinctive name" immunity. ACT, §8(4-1). Some states provide for special labeling of "soaked or bleached" canned goods. See, *e.g.*, MICH. COMP. LAWS (1915) c. 124 ¶6487, §14.

[88] BILL, §6(c).
[89] BILL, §2(i).
[90] BILL, §2(i).
[91] BILL, §2(j).

The subsection under discussion does more than add to the list of media; it lays strong hold upon those whose chief stock in trade is criticizing the competitor's wares. For note that under the wording of subsection (a) misbranding occurs if the labeling on a food, drug, or cosmetic is false or creates a misleading impression regarding "*any* food, drug, or cosmetic."[92] That the bill here creates a statutory crime of trade libel and disparagement of goods appears more evident if this labeling section be contrasted with the definition in the present Act and that given in the bill of false advertising of a food, drug, or cosmetic as occurring when the advertisements thereof are false regarding "*such* food, drug, or cosmetic."[93] The change is important. The provision is also novel. Under the present Act, *United States v. Johnson*[94] is still a controlling authority for the point that the present federal law despite its broad terms aims solely at misrepresentations as to the identity, quality, or composition of the article itself, and is not concerned with what lies the label or the circulars may make regarding other products in fields either vertically or horizontally competitive.

The phrase of the labeling clause which seems to have captured public attention and to have received not a little criticism is that which recites that misbranding occurs where the labeling "by ambiguity or inference creates a misleading impression."[95] Similar language appears in the bill's definition of false advertising.[96] Several problems and difficulties readily come to the fore. Suppose the statements on A's label create false impressions not in the minds of consumers or purchasers generally but on special classes of such persons? Suppose the label conveys the full truth in one geographical section of the country but creates false impressions in another? Consider also the situation where A's labeling by itself is not misleading but creates a false impression because of:

(1) statements made by A on other labels of the same product;

(2) statements made by A on labels of other products;

(3) statements made by B. (*e.g.* a trade association) regarding the product. The indications are that in all the cases suggested a misbranding occurs.[97] This conclusion is supported by the broad language of the bill and a number of decisions. As a matter of fact, the term "misleading" in the present Act has been interpreted as including the creation of a "false impression" so that decisions thereunder are relevant and point somewhat to this conclusion.

In *United States v. American Laboratories,*[98] the defendant had marketed a product called "Bad-Em Salz." The statements made concerning the product were technically true, but because of the belief prevalent among many people that Carlsbad or Bad-Ems waters had medicinal property, the product was seized as misbranded. The defendant argued that since the statements were strictly true they were not false

[92] BILL, §6(a).

[93] BILL, §9(a). The misbranding provision of the bill contrasts also in this respect with the present Act. *Cf.* ACT, §8 ("Statement, design, or device regarding such articles"). Its primary purpose was to cover false claims for other products sold by the *same* manufacturer.

[94] *Supra* note 50.

[95] BILL, §6(a).

[96] *Id.* §9(a).

[97] See *infra* note 102.

[98] 222 Fed. 104 (E. D. Pa. 1915).

or misleading within the meaning of Section 8 of the present Act, and as the result claimed to follow from the use of the medicine was a matter of opinion there was no basis for the charge. The court denied the contention and said:

"It is not a necessary condition of a finding of guilt that the statement of what the drug is should be a statement flatly and baldly false but that the word 'misleading' in the act has its function, which is to bring the statement within the inhibition of the statute *if it is such as to create or lead to a false impression* in the mind of the reader as to what the ingredients or the composition of the drug are."[99] (Italics ours).

Again, under the present Act, using the term "Extra Dry Champagne" on a label affixed to a bottle with a foreign "dress" has been held a misbranding on the ground that the combination created in the mind of the consumer "the impression that they were purchasing a foreign and not a domestic product."[100] Under the present Act also a departmental regulation provides that an article so labeled as to convey the impression that all of the ingredients are declared is misbranded if the list be incomplete.[101]

The "impression" phrase is therefore no radical innovation in the law of food and drug control. Moreover, under the "unfair trade" provisions of the Federal Trade Commission Act, the Federal Trade Commission has issued cease and desist orders not only where direct falsehood has been used as a competitive weapon but also where the advertising or label created false impressions because of circumstances extrinsic to the censured publicity.[102] That the law within recent years has been moving into the field of "puffing," hitherto so sacrosanct in public and private law, is attested also by a number of state statutes prohibiting the use of terms suggestive of falsehood.[103] The constitutionality of the clarification of the present law as respects false impressions, or of the extension if it be such, cannot be seriously questioned.[104]

[99] *Id.* at 108.

[100] Schraubstadter v. United States, *supra* note 44.

[101] *Cf.* Reg. 14(h). See also U. S. v. Johnson, *supra* note 50, at 498, 31 Sup. Ct. at 628.

[102] Royal Baking Powder Co. v. F. T. C., 4 F. T. C. 1 (1921), *aff'd*, 281 Fed. 744(C. C. A. 2d, 1922). The court deemed a change from a cream of tartar baking powder widely advertised as such to a phosphate baking powder as an attempt to sell an inferior product "under an impression" caused by the prior advertisements, which "impression" came under the Commissioner's censure though the phosphate advertising was literally true. *Id.* at 753. For the background of this particular deception, see CHASE & SCHLINK, *op. cit. supra* note 56, at 150. *Cf.* also Consolidated Book Publishers' Inc. v. F. T. C., 53 F. (2d) 942 (C. C. A. 7th, 1931); (1933) 31 MICH. L. REV. 804, 815.

[103] Thus statutes regulating the organization of coöperative associations forbid the use of "coöperative" in the title of groups not formed under statutes. Similar restrictions exist on the title of credit unions and banks. Alabama forbids auctioneers to employ cappers or boosters to raise bids. See Note (1930) 43 HARV. L. REV. 945, 948 n. 28-34. See also, W. Va. Rev. Code (Michie, 1932) §1370 (6) (8) (article deemed misbranded "if it is sold under a coined name and does not contain some ingredient suggested by such name or contains only an inconsiderable quantity"). *Cf.* CAN. REV. STAT. (1927), c. 76, §8(3) (compounds and imitations must be so labelled "as not to be likely to deceive").

[104] In Jasnowski v. Connolly, 192 Mich. 139, 158 N. W. 229 (1916), a "Printers' Ink" statute was attacked on the ground that while proper for the legislature to score false advertising, it could not prohibit "deceptive" advertising as what might give A an erroneous impression might not tend to deceive B. The statute was upheld. The libel which was sustained in Seven Cases of Eckman's Alterative, *supra* note 29, charged, *inter alia,* that "the statement 'we know it has cured' and that 'it will cure tuberculosis' is false,

The general provision that the labels of all articles within the compass of the bill if in packaged form recite the name and place of business of the manufacturer, seller, or distributor and give an accurate statement of the quantity but foreshadows and indicates what is one of the outstanding contributions of the bill—the duty to reveal the truth on the label as contradistinguished from the present frail duty (except in special circumstances) not to place mendacious statements upon the label. The deception which resulted from the failure of the present law in general to demand a standard higher than "do not lie" has already been noted. Under the bill, if enacted, no longer could the adroit vendor put on the market a food or drug package embellished with pretty colors and fancy design and pleasant trade name but with a complete failure actually to disclose and indicate more concretely just what is the nature of the product. Nor would shipment across state lines without labels in order to affix deceptive labels within the state of destination succeed as an evasive manoeuver.

Sections 7 and 8 of the bill are clear in their import. Food labels from the enactment of the bill must:

(1) give the name of the food in terms defined by regulations fixing the identity of the product if the food purports to be or is represented as such a food;[105]

(2) state the standard of quality of the food if the food purports to be or is represented as a food for which regulations have been prescribed both fixing such standard and requiring a statement of the standard;[106]

(3) give the common name of the food if any and the common name of each ingredient in order of predominance by weight if no definition of identity has been made by the regulations, and in addition such other information as the Secretary of Agriculture may deem necessary to protect the public from deception.[107]

In similar fashion, an analysis of the terms of the bill shows that drug packages must have labels which:

fraudulent and misleading in this, to wit, that it conveys the impression to purchasers that said article of drugs will cure tuberculosis." *Id.* at 514, 36 Sup. Ct. at 192. The "impression" test is also used in the Federal Reserve Bank Act, 44 STAT. 628 (1926), 12 U. S. C. A. §586 (no bank, banking association or trust company not a member of the Federal Reserve system shall ". . . publish or display any sign, symbol, or advertisement reasonably calculated to convey the impression that it is a member of such system."). *Cf.* N. R. A. Code for Petroleum Industry, Rule 25 ("implication which leads to a false or incorrect conclusion"); Advertising Review, Code of Advertising Practices ("false statements or misleading exaggerations," "indirect misrepresentation of a product or service through distortion of details, either editorially or pictorially").

[105] BILL, §7 (d).

[106] *Id.* §7 (e). It is important to notice that the purporting or representing to which the bill refers need not be made upon the label or the package. The article will be subject to these affirmative disclosure requirements if the representation be made orally, by advertisements or otherwise. *Cf.* Weeks v. U. S. *supra* note 5. On the necessity for the affirmative disclosure, see *Must the Housewife Beware?* (DEPT. AGR. Aug. 18, 1933); Barber, *Are Foods Truthfully Labelled?* (1933) 11 HYGEIA 597.

[107] BILL, §7 (f). For an analogous broad power of an administrative body to compel statements deemed by it necessary or appropriate in the public interest, see NATIONAL SECURITIES ACT, §10 (3). It should be carefully noted that the disclosure of ingredients in the case of foods is restricted to (3) above. This seems ignored in many trade journal discussions of the bill. For opposition to the disclosure even in this instance, see Jordan, CONFECTIONER'S J., Nov. 1933, 28.

(1) indicate the quantity or proportion of some sixteen narcotic substances or their derivatives contained therein in a form prescribed by the regulations, the name of such narcotics, and in juxtaposition with the name and statement of composition the words: "Warning—May be habit forming";[108]

(2) state the quantity or proportion of ethyl alcohol, ethyl ether, or chloroform present in the drug;[109]

(3) state the common name of the drug, if any there be, and the name and quantity or proportion of each medicinal or physiologically active ingredient in the case of all drugs whose name is not the same or imitative of names in the United States Pharmacopoeia or National Formulary or supplements thereto;[110]

(4) give such statements as are required by the above mentioned Pharmacopoeia or National Formulary where its name is the same as, or simulates the name of drugs defined in, those volumes;[111]

(5) give precautions where the drug is liable to deterioration and the Secretary of Agriculture so directs;[112]

These provisions as to disclosure required on the label are the more remarkable if it be noted that, under the bill, the "label"[113] means both that on the immediate container and also that on the outside container, if any there be, of the retail package. Possibly the proposed law would be satisfied if the disclosure be made on either type of label; but such a construction would move contrary to the design of the draftsmen of the bill to afford the consumer a maximum of protection. Two further disclosures must be made as to certain drugs, but these may be made in the "labeling" and not necessarily on the "label." If a drug is not a pharmacopoeia preparation, its labeling

[108] BILL, §8 (b). This subsection applies only where the drug is intended for internal use and hence will not apply to inhalants. *Cf.* U. S. v. 11 Cartons, Drug, etc., *supra* note 25. §8 (b) omits alcohol, chloroform and acetanilid from the prior list of drugs so that drugs containing them need not give the habit-forming warning. But see note 109, *infra*. To the ten drugs now covered by the Act (see note 25, *supra*), the bill adds barbital, bromal, carbormal, coca, chloral (Act has chloral hydrate), paraldehyde, peyote, and sulphonmethane. Where derivatives are present, the name both of the derivative and the principal drug must be given. That the present list of drugs has proved antiquated is indicated by state statutes which have added to the federal list. See, e.g., COLO. ANN. STAT. (Courtright, 1930) c. 1, §7 (2) (any harmful coal tar derivative); IDAHO COMP. STAT. (1919) §1691 (2) (phenacitin); IND. STAT. ANN. (Burns, 1926) §8228 (phenacetine, antipirine); MD. ANN. CODE Bagby, 1924) art. 43, §192 (holocaine, novocaine, alypin, codeine, antifebrin, acetphenetidin, phenacetine, antipyrine); NEB. COMP. STAT. (1929) §81-904 (phenacetine, antipyrine, belladonna); N. J. COMP. STAT. (Supp. 1924) §81-4 (acet-phenetidine, phenacetin, antipyrin); N. D. COMP. LAWS (Supp. 1925) §2889b6 (any narcotic or habit-forming drug); PA. STAT. (Supp. 1928) §9340 (phenacetine, antipyrine). On the general legal development of the Harrison Narcotic Act, see Note (1928) 13 CORN. L. Q. 627.

[109] BILL, §8 (c). This provision applies to inhalants as it is not prefaced by the words "if it is for internal use." But the bill fails to have any analogous provision for foods. The declaration of ethyl ether is wholly new.

[110] BILL, §8 (e). Note the limited class of drugs to which this disclosure of ingredients applies.

[111] BILL, §8 (f).

[112] BILL, §8 (g). The Secretary is authorized after notice and hearing to designate which drugs are liable to deterioration.

[113] BILL, §2 (h). But the "label" of the bill does not include pamphlets within the package. *Cf.* §2 (h) and §2 (i). The affirmative disclosure provisions, therefore, will not be satisfied by recitals made in such pamphlets.

must contain "complete and explicit directions for use."[113a] If the drug purports to be or is represented as a germicide, bactericide, disinfectant, or antiseptic, its labeling must state each use and, plainly and conspicuously and in juxtaposition therewith, the method and duration of application necessary to kill micro-organisms.[114]

We may postpone the question of the constitutional validity of the disclosure provisions to the extent that the question is affected by the delegation to the Secretary of Agriculture of the power to make regulations.[115] What is first pressing is whether or not the federal government may compel such disclosure. The source of federal authority is, of course, the commerce power and the much mooted collateral power thereunder to make "police" regulations regarding the products which are the subject of interstate commerce. The bar to the unrestrained exercise of that power is the due process provision of the Fifth Amendment. The property rights which the disclosure provisions invade may be in many cases not only trade secrets and trade formulae but also the more general right to retain present labels and trademarks, to continue present methods of distribution and the good will incident thereto, and to be spared the printing expenses and other costs which the disclosure will necessitate.[116] This latter may not be inconsiderable if it be observed that to meet some requirements of the statutory disclosure, qualitative analyses of the product must be made, and made recurrently.[117]

Fortunately, legal decision on the point is not wanting. The very necessity for a federal law demanding that more information be given to the consumer as to what he buys and that such information be more than puffing and hokum has been presaged by the increasing number of state statutes which have insisted on affirmative labels as to the ingredients of various products ranging from gasoline and fertilizers to cold storage eggs and artificially flavored soft drinks.[118] And the decisions dealing with these statutes run to the effect that compulsory disclosure of the ingredients of the food or drug and the standard of their quality may be demanded without violating the due process inhibition. Thus in *Corn Products Refining Company v. Eddy,*[119] pursuant to the Foods and Drugs Law of Kansas and regulations[120] adopted

[113a] BILL, §8 (d). The Secretary is empowered to exempt drugs by regulation from the requirements of this subsection. Note its relation to §4 (a). It excludes germicides, antiseptics, etc., which are subject to subsection (i).

[114] BILL, §8 (i). The definition seems too rigorous. For the present difficulties in regard to antiseptics, see *supra* note 71. Under subsection (i) drugs are not misbranded if the germicide, bactericide, disinfectant, or antiseptic is represented as intended for specific kinds of micro-organisms only and the labeling states conspicuously and in juxtaposition the method and duration of application to kill these kinds.

[115] See *infra* p. 107.

[116] See DRUG TRADE NEWS, Oct. 16, 1933, at 26, 55; *id.* Nov. 13, 1933, at 35.

[117] But Section 26 (a) of the Bill provides that its effective date shall be six months after the date of approval. In many instances, the six months period should be sufficient time in which to alter distribution methods.

[118] See *supra* note 103.

[119] *Supra* note 4.

[120] The regulation involved provided as follows: "Manufacturers of proprietary foods are required to state upon the label the names and percentages of the materials used, so far as is necessary to secure freedom from adulteration and misbranding: (1) In the case of syrups, the principal label shall state

under it, the State Board of Health had notified the plaintiff corporation's agents that unless they stated, on the label placed on its product, the percentage of each ingredient of which it was composed, they would be arrested and prosecuted. The corporation manufactured a proprietary table syrup composed of corn syrup or glucose, molasses and sorghum. The plaintiff sued to enjoin the enforcement of the law, alleging its unconstitutionality. The Supreme Court of the United States held for the defendants in an unanimous opinion.

"It is, however, urged that since plaintiff's syrup is a proprietary food, made under a secret formula and sold under its own distinctive name, and since it contains no deleterious or injurious ingredients, the effect of the regulation in requiring plaintiff to disclose upon the label the ingredients and their proportions amounts to a taking of its property without due process of law. Evidently the purpose of the requirement is to secure freedom from adulteration and misbranding; the mischief of misbranding being that purchasers may be misled with respect to the wholesomeness or food value of the compound. And it is too plain for argument that a manufacturer or vendor has no constitutional right to sell goods without giving to the purchaser fair information of what it is that is being sold. The right of a manufacturer to maintain secrecy as to his compounds and processes must be held subject to the right of the State, in the exercise of its police power and in the promotion of fair dealing, to require that the nature of the product be fairly set forth."[121]

Legislation requiring disclosure of ingredients on the label or to executive officers, has been upheld by the state and federal courts.[122]

It should be observed that the present bill is worded similarly to the Kansas regulation. It also compels in the instances noted a statement of the quantity or proportion of various ingredients and thus storms the sanctum of the trade formula. But *Corn Products Refining Company v. Eddy* would seem decisive. In an earlier case[123] before the Supreme Court the Court had before it a state statute requiring manufacturers of mixed paints to label the ingredients composing them. The man-

definitely, in conspicuous letters, the percentage of each ingredient, in the case of compounds, mixtures, imitations, or blends. When the name of the syrup includes the name of one or more of the ingredients, the preponderating ingredient shall be named first."

[121] *Id.* at 431, 39 Sup. Ct. at 327.

[122] On labels: Standard Stock Food Co. v. Wright, *supra* note 4, (name and percentage of diluent); State v. Aslesen, 50 Minn. 5, 52 N. W. 220 (1892), writ of error dismissed per stipulation, 163 U. S. 676 (1895) (names of ingredients of lard substitutes); State v. Buck Mercantile Co., 38 Wyo. 47, 264, Pac. 1023 (1928) (amount of virgin wool); Steiner v. Ray, 84 Ala. 93, 4 So. 172 (1888) (ingredients of fertilizer); Alcorn Cotton Oil Co. v. State, 100 Miss. 299, 56 So. 397 (1911) (hulls, sawdust, etc. in cotton seed). To executive officers: Fougera & Co. v. City of New York, *supra* note 4; Crescent Mfg. Co. v. Wilson, 233 Fed. 282 (N. D. N. Y. 1916). The interpretation adopted in the latter case that the New York statute required disclosure of ingredients of compounds was not accepted by the New York courts. *Cf.* People v. Durkee, 189 App. Div. 276, 178 N. Y. Supp. 614 (1919); *aff'g* 101 Misc. 331, 166 N. Y. Supp. 987 (1917). A statement of ingredients does not compel a disclosure of formula. Savage v. Jones, *supra* note 4 (Supreme Court refuses to express opinion on constitutionality of formula disclosure). In Patapsco Guano Co. v. North Carolina, 171 U. S. 345, 18 Sup. Ct. 862 (1898), and Armour & Co. v. North Dakota, 240 U. S. 510, 36 Sup. Ct. 440 (1916), the Supreme Court dealt with statutes requiring disclosure of ingredients but the constitutional problem was not considered. *In re* Ware, 53 Fed. 783 (C. C. D. Minn. 1892), the court held that forcible disclosure was possible only when the ingredient was shown to be deleterious. But this contention has been definitely rejected. *Cf.* State v. Aslesen, *supra*, and U. S. v. 11 Cartons, Drug, etc., *supra* note 25, at 448.

[123] Heath & Milligan Mfg. Co. v. Worst, 207 U. S. 338, 28 Sup. Ct. 114 (1907).

ufacturer contended that to meet the terms of the statute it would have to subject each and every can of mixed paint to a chemical analysis prior to the labeling. The Court acknowledged the difficulty but termed it "a burden maybe, but unremediable by the courts—maybe, inevitable in legislation directed against the adulteration of articles or to secure a true representation of their character or composition."[124]

The constitutionality of the disclosure of some of the other data required is not so clearly established. In particular, the general requirement that foods, drugs, and cosmetics in packaged form must have a label stating the name and place of business of the manufacturer, seller or distributor, may have to run the judicial gauntlet. State statutes requiring that eggs imported from a foreign country be marked "Imported Eggs" and requiring a similarly marked placard at the place of their sale have been held invalid on the ground that there was an insufficient nexus between the place of origin and the character of the product as to require its disclosure.[125] For similar reasons, a statute requiring on "prepared foods" the true name of the manufacturer and location of factory has fallen,[126] and the requirement of a "Convict Labor" label for goods manufactured in prisons has been held beyond the state's police power irrespective of the question of trespass on Congressional control over interstate commerce.[127] The insistence on the statement "Irregular Container" for non-standard containers of grapes has been held an unconstitutional attempt to regulate the manner of marketing.[128] Most of these decisions, however, will not bear the closest examination, and there is a considerable if not equal body of authority holding a forcible disclosure of source to be within constitutional bounds.[129] In the main, the decisions striking down such forcible disclosure move largely on a false hypothesis: the police power is evoked in food and drug regulation solely to protect the consumer's health.[130] There has been too little recognition of the fact that food

[124] *Id.* at 359, 28 Sup. Ct. at 121.

[125] *Ex parte* Foley, 172 Cal. 744, 158 Pac. 1034 (1916); State v. Jacobson, 80 Ore. 648, 157 Pac. 1108 (1916) (rested largely on state invasion of interstate commerce).

[126] Jewett Bros. & Jewett v. Smail, 20 S. D. 232, 105 N. W. 738 (1905).

[127] People v. Hawkins, 157 N. Y. 1, 51 N. E. 257 (1898); *In re* Opinion of the Justices, 211 Mass. 605, 98 N. E. 334 (1912). See Note (1925) 25 COL. L. REV. 814.

[128] Mattei v. Hecke, 99 Cal. App. 747, 279 Pac. 470 (1929). Note also that the bill does not require the place of manufacture or packing to be disclosed but the place of business of the manufacturer, packer, etc. BILL, §6 (b).

[129] *In re* Bear, 216 Cal. 536, 15 Pac. (2d) 489 (1932) (imported eggs sign); Amos Bird Co. v. Thompson, 274 Fed. 702 (W. D. Wash. 1921) (imported eggs sign; court rests largely on Corn Products v. Eddy, *supra* note 4); Parrott & Co. v. Benson, 114 Wash. 117, 194 Pac. 986 (1921) (imported eggs sign); Logan v. Alfieri, 148 So. 872 (Fla. 1933) (name of producer on milk containers proper, but other names could not be excluded); People v. Bishopp, 106 App. Div. 266, 94 N. Y. Supp. 773 (1905) (names of raiser of cattle, shipper, and point of shipping); People v. Windholz, 92 App. Div. 569, 86 N. Y. Supp. 1015 (1904) (name and place of business on vinegar label, *semble* proper); State v. Niles, 78 Vt. 266, 62 Atl. 795 (1906) (name of owner transporting deer on tag). The source disclosure provision appeared in statutes approved in the following cases: City of Chicago v. Schmidinger, 243 Ill. 167, 90 N. E. 369 (1909), *aff'd*, 226 U. S. 578, 33 Sup. Ct. 182 (1913); State v. Sherod, 80 Minn. 446, 83 N. W. 417 (1900).

[130] "A can of corn bearing Jewett's 'Guaranteed' brand would not be relieved of any injurious properties by the mere addition of the canner's name and address." Jewett Bros. & Jewett v. Smail, *supra* note 126, at 243, 105 N. W. at 741. "It is not claimed that there is any difference in the quality of this

and drug control is concerned with the protection of the consumer's pocketbook as well as his digestion. Granting, *arguendo,* that disclosure of source is insufficiently related to problems of health, can the same be said of its relation to the problem of honesty? The fact that incidentally the new Act would give blessing and protection to those who wish to forward the interests of regional products should not condemn a clause whose chief object is to prevent economic fraud.

Provisions other than compulsory disclosure in the misbranding sections remain to be noted.[131] The law is finally to take direct cognizance that forms of deception other than the verbal may play havoc with the return which the purchaser secures for his dollar. Accordingly, foods and drugs are to be deemed misbranded if their containers are so made, formed, or filled to mislead the unwary purchaser.[132] The term "container" does not seem to be defined in any section of the bill. The definition of "label," however, refers to both the immediate container of the food, drug, or cosmetic, and the outside container. The inference, despite the absence of definition, would seem to be that the false container prohibition includes both types of receptacles. It is not as certain that "container" would include the "dress" and wrappings about the receptacle. A question may also arise if false coloring of a bottle is prohibited by the provisions of the bill.[133] In addition to the general requirement of undeceptive containers, a food package will be misbranded if its contents fall below the standard of fill prescribed by regulations of the Secretary of Agriculture,[134] while drugs whose names are recognized in the United States Pharmacopoeia or National Formulary or any supplement thereto or whose names simulate the names in those volumes must be packaged as prescribed therein,[135] and drugs liable to deterioration must be packaged as directed by the regulations.[136]

One reads the bill in vain for the statutory exceptions as to the distinctive names, compounds, imitations, or blends. The protection for imitation food products has been retained where the label bears the word "imitation" in juxtaposition with and in type of the same size and prominence as the name of the food imitated;[137] in all other respects the statutory exceptions would no longer obtain.

The data of which the bill forces disclosure on the labels of drugs has already been considered. The bill is not satisfied with this important measure of protection but

scrubbing brush when compared with one of the same grade or character made outside the prisons." People v. Hawkins, *supra* note 127, at 7, 51 N. E. at 258. *Cf.* also the reasoning of the courts in the other cases cited *supra* notes 125-127.

[131] The bill repeats the present prohibition against offering food and drugs which are imitations or offered for sale under the name of other food or drug articles. *Cf.* ACT, §8, with BILL, §7 (b), §8 (h). The only difference is that under Section 8 of the Act the food was misbranded if offered under the "distinctive" name of another food; the bill deletes the word "distinctive." To this extent, the bill has broadened the violation.

[132] BILL, §7 (a-1), §8 (h). *Cf.* CAN. REV. STAT. (1927) c. 76, §7 ("if the package is deceptive with respect to design, construction, or fill").

[133] The language of the bill is directed only at the making, forming, and fill of the container.

[134] BILL, §7 (a-1).

[135] *Id.* §8 (f). Drug packaging is, in fact, seldom prescribed in these volumes.

[136] *Id.* §8 (g).

[137] *Id.* §7 (b).

recites two further special requirements in the case of drugs. First, if the labeling of a drug bear the name of any disease for which the drug is not a specific cure but is a palliative, it must bear in juxtaposition with such name and in letters of the same size and prominence a statement that the drug is not a cure for such disease.[138] A similar proviso appears in the definition of false advertising of drugs.[139] The purpose of this provision is praiseworthy and in line with the policy of the bill to place affirmative duties upon vendors and manufacturers. On the other hand, the provision seems too sweeping. If it be remembered that labeling includes at least the circulars, pamphlets, etc., enclosed within the package, the force of this provision may be that every time a disease is mentioned in any connection whatever, the cry, "this drug is no cure," must be added. So interpreted, the restriction would be onerous.

The second special proviso for drugs is as follows: the labeling (and advertising) must not include "any representation, directly or by ambiguity or inference, concerning the effect of such drug which is contrary to the general agreement of medical opinion."[140] The effect of this proviso is to delete the words "and fraudulent" from the Sherley Amendment. In other words, by virtue of this section, the mere expression on a label or in an advertisement of a representation contrary to the general agreement of medical opinion becomes a violation of the federal law; courts are no longer to inquire into the mental state of the person responsible for the label or advertisement. The condition of affairs requiring the change has been discussed elsewhere.[141] Making the state of opinion in the medical world determinative of falsity as to statements concerning the effects of drugs seems radical: actually, the present Act has ventured that far. For under judicial decision, the therapeutic vatication scored by the present Act is not "false" if there exist a real difference of opinion between rival schools of medical practitioners;[142] *aliter*, if the consensus of the medical world denies its truth.[143] The contribution of the bill in this regard is that a statutory definition of falsity is provided, which, capable of explanation by regulation, should result in greater uniformity and success of administration. The interesting question is: can Congress deny movement in interstate commerce to products concerning which there have been made not false *and* fraudulent representations of opinion but merely false representations? The point was argued before the Supreme Court in *Seven Cases of Eckman's Alterative v. United States*[144] where the libelee attacked the Sherley Amendment on the ground that it entered the domain of speculation and by uncertainty deprived the vendor of drugs of liberty and property in violation of the Fifth Amendment and did not permit the laying of a definite

[138] BILL, §8 (a-1). For opposition to this feature of the bill, see DRUG TRADE NEWS, Sept. 18, 1933, at 1; *id.* Oct. 2, 1933, at 33.

[139] BILL, §9 (b-1).

[140] *Id.* §8 (a-2).

[141] See *supra* p. 81.

[142] U. S. v. Tuberclecide Co., *supra* note 55; Kar-Ru Chemical Co. v. U. S., 264 Fed. 921 (C. C. A. 9th, 1920); see Seven Cases, Eckman's Alterative v. U. S., *supra* note 29, at 517, 36 Sup. Ct. at 193.

[143] U. S. v. Chichester Chemical Co., *supra* note 53.

[144] *Supra* note 29.

charge as required by the Sixth. The Court held that the objection proceeded on a misconstruction of the statute and that Congress by using the terms "false and fraudulent" had deliberately excluded the field of honest differences of opinion between practitioners. The Court, therefore, did not pass on the question whether Congress could control "false" opinion.[145] There is some slight indication in the decision that the Court entertained some doubt regarding the latter.[146] *American School of Magnetic Healing v. McAnnulty*,[147] which has been urged against the Congressional power cannot be deemed authoritative, as the question answered in the negative in that case was whether the mail fraud statute[148] applied to persons securing money through the mails for mental healing treatments where it was shown that such persons were *honest* in their belief and that a great many people believed in the efficacy of the treatment. Indeed the use interchangeably in the *McAnnulty* case of "false or fraudulent pretenses" and "false and fraudulent pretenses"[149] without cognizance that the difference might be a constitutional law demarcation supports somewhat the validity of the suggested change. Certain language of Mr. Justice Holmes in *United States v. Johnson*[150] mildly indicates the possibility of such a constitutional demarcation. Since that language was used in a decision construing the statute inapplicable to merely false opinion, his language should not be given too great force. It is important to note that the minority led by Hughes, J., specifically adverting to the question of constitutionality felt that statements *prima facie* of opinion became downright falsehoods of fact when contrary to general opinion and in no sense expressions of judgment beyond Congressional

[145] *Id.* at 517, 36 Sup. Ct. at 193.

[146] "The amendment of 1912 applies to this field [*i.e.* of false and fraudulent opinion] and we have no doubt of its validity." *Id.* at 518, 36 Sup. Ct. at 193.

[147] 187 U. S. 94, 23 Sup. Ct. 33 (1902).

[148] "The Postmaster General may, upon evidence satisfactory to him that any person is engaged in conducting any fraudulent lottery . . . or in conducting any other scheme or device for obtaining money through the mails by means of false or fraudulent pretenses, representations, or promises instruct postmasters. . . ." 17 STAT. 322 (1872), 28 STAT. 964 (1895), 39 U. S. C. A. §259.

[149] See opinion of Peckham, J., in American School of Magnetic Healing v. McAnnulty, *supra* note 147 at 104, 23 Sup. Ct. at 37.

[150] "In view of what we have said by way of simple interpretation we think it unnecessary to go into considerations of wider scope. We shall say nothing as to the limits of constitutional power, and but a word as to what Congress was likely to attempt. It was much more likely to regulate commerce in food and drugs with reference to plain matter of fact so that food and drugs should be what they professed to be, when the kind was stated, *than to distort the uses of its constitutional powers* to establishing criteria in regions where opinions are far apart. See School of Magnetic Healing v. McAnnulty." Holmes, J., in U. S. v. Johnson, *supra* note 50, at 498, 31 Sup. Ct. at 628 (italics ours).

It is difficult to escape the suspicion that behind these doubts lies some fear of invading the right of free expression protected by the First Amendment, even though no reference thereto appears in the opinions.

[151] "Nor does it seem to me that any serious question arises in this case as to the power of Congress. I take it to be conceded that misbranding may cover statements as to strength, quality, and purity. But so long as the statement is not as to matters of opinion, but consists of a false representation of fact—in labeling the article as a cure when it is nothing of the sort from any point of view, but wholly worthless—there would appear to be no basis for a constitutional distinction. It is none the less descriptive—and falsely descriptive—of the article. Why should not worthless stuff, purveyed under false labels as cures, be made contraband of interstate commerce as well as lottery tickets?" Hughes, J., in U. S. v. Johnson, *supra* note 50, at 506, 31 Sup. Ct. at 631. Harlan and Day, JJ., concurred with Hughes, J. The fact that the

control.[151] Where, in the Court's own words, a "consensus of opinion" has shown a product unquestionably harmless with respect to its contemplated uses, a state cannot completely prohibit its presence in food.[152] It is difficult to see why the converse should not be true; the due process limitation should not stand in the way of legislative power striking representations contrary to that "consensus of opinion." Whether "the general agreement of medical opinion" is a sufficiently definite standard in a criminal statute is another matter.

United States v. Johnson has been relied upon by those who contend that in no case does the present Act reach representations of opinion. Fraudulent statements of opinion being misrepresentations of a mental state are patently representations of fact and could have been reached without the Sherley Amendment. The significance of that amendment—it is submitted—lay largely in its inclusion of opinion representations in the field of therapeutic effects of drugs which technically were not statements of identity, composition, or quality. The bill adopts language which is designed to prevent a construction limiting its prohibitions to representations of fact. In the case of advertisements, representations of opinion are explicitly included.[153] In misbranding, however, the term "opinion" is not employed, thus opening the way for the construction that no extension is made to the prior law. However, the terms "ambiguity or inference" taken with the "impression" test may nullify the effect of such omission and cover anything contained on the labeling which produces a misleading impression, regardless of distinctions stemming out of the law of deceit.[154] So construed, the constitutional issue regarding the power of Congress to prevent the expression of misleading opinions which are not fraudulent is squarely raised. The weak dicta in the cases which have been reviewed, especially in the light of the dissent of Mr. Justice Hughes in *United States v. Johnson,* do not preclude a decision sustaining these sections. The statute, it will be noted, outside the field of therapeutic effects, leaves the definition of falsity of opinion to the courts.

FALSE ADVERTISING UNDER THE BILL

Reference has been made *passim* to the false advertising provisions of the bill. As noted, dissemination in interstate commerce of false advertisements inducing the purchase of food, drugs or cosmetics and the dissemination by any means of false advertisements inducing the sale of such articles in interstate commerce are prohibited. "False advertisement" is used as a term of legislative art. It is an advertisement which is untrue in any particular or misleading regarding the food, drug, or

bill makes general medical opinion the test of the falsity other than the general point of view mentioned by Hughes, J., should not make a constitutional difference. *Cf.* U. S. v. Chichester Chemical Co., *supra* note 53, where the opinion of the medical world was deemed determinative of the falsity of a therapeutic representation under the Act.

[153] See Price v. Illinois, 238 U. S. 446, 452, 35 Sup. Ct. 892 (1915).

[153] The term advertisement includes all representations of fact or opinion disseminated in any manner or by any means other than by the labeling. BILL, §2 (j).

[154] See Handler, *False and Misleading Advertising* (1929) 39 YALE L. J. 22, 32.

cosmetic advertised.[155] It is an advertisement of a drug which does not state that the drug is not a cure for a mentioned disease.[156] It is an advertisement of a drug which contains representations contrary to the general agreement of medical opinion.[157] Finally, "false advertisement" of a drug is one representing it directly or by ambiguity or inference to have any effect in the treatment of thirty-six named diseases, ailments, and disorders beginning with albuminuria and ending with whooping cough.[158] The ground for this last prohibition is stated as the legislative declaration that Congress wishes to discourage the public advertisement for sale in interstate commerce of drugs for diseases wherein self-medication may be especially dangerous or patently contrary to the interests of public health. An exception thereto relates to advertisements disseminated to members of the medical and pharmacological professions only or as to advertisements appearing in scientific periodicals.[159] There is a proviso that when medical science makes self-medication safe as to any of the "diseases" enumerated, the Secretary of Agriculture may authorize the advertisement of drugs for such disease, subject to such conditions and restrictions as he may deem necessary in the interests of the public health.[160] A procedure is also provided by which the Secretary may add "diseases" to the *index expurgatorius*.[161]

If this bill passes, it will not be the first attempt on the part of the Federal Government to control advertising. An examination of the statute books reveals that such advertising is already controlled under the Aliens and Citizenship Law,[162] the Lotteries Law,[163] the National Prohibition Act,[164] the Federal Reserve Bank Act,[165] the Federal Farm Loan Act[166] and the Securities Act.[167] The need for controlling false advertising relating to foods, cosmetics, and especially drugs seems particularly urgent. The civil remedies for the false advertising of these articles are inadequate and serve as the slightest of deterrents.[168] The Federal Trade Commission is ham-

[155] BILL, §9 (a). But the falsity here must be regarding the product itself. As already noted the advertisement is false which creates misleading impressions. On the whole question of advertising and the bill, see Tugwell, *Advertising and the New Food and Drugs Bill*, EDITOR AND PUBLISHER, Nov. 1933. For opposition to the bill's prohibition of false advertising, see Nichols, *Beat the Tugwell Bill!* (1933) 175 PRINTERS' INK 6.

[156] BILL, §9 (b) (1). For an unduly critical analysis of this section, see (1933) 33 DRUG AND COSMETIC INDUSTRY 225.

[157] BILL, §9 (b) (2).

[158] *Id.* §9 (c). The "diseases" named are: albuminuria, appendicitis, arteriosclerosis, blood poison, bone diseases, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas, gallstones, heart diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis media, paralysis, pneumonia, poliomyelitis, prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infections, smallpox, tuberculosis, tumors, typhoid, uremia, venereal diseases, and whooping cough.

[159] *Id.*

[160] *Id.*

[161] *Id.*

[162] 39 STAT. 879 (1917), 8 U. S. C. A. §142.

[163] 28 STAT. 963 (1895), 18 U. S. C. A. §387.

[164] 41 STAT. 313 (1919), 27 U. S. C. A. §29, 30.

[165] *Supra* note 104.

[166] 44 STAT. 628 (1926). 12 U. S. C. A. §584.

[167] *Cf.* NATIONAL SECURITIES ACT, §2 (10), 5 (1).

[168] See Handler, *supra* note 154, at 23. As illustrative of the particular difficulties in recovering for damages through falsely advertised foods, see Alpine v. Friend Bros., Inc., 244 Mass. 164, 138 N. E. 553 (1923) ("grown folks and children alike may eat as many slices as they please without fear of harm" not a representation that specific slice did not contain a piece of tin).

pered by the limited power granted by its organic statute, and can intervene in the interests of unfair competition, but not solely on behalf of the consumer's health.[169] The Printers Ink Model Statutes[170] and other state legislation on false advertising have sonorous language implying a Sinaitic force which unfortunately is lacking. Actually, these statutes are in terms usually confined to misrepresentation of fact, leaving the door open to "puffing," the advertiser's godsend.[171] In practice, so far as their application is to patent medicine advertising, they are generally restricted to grossly fraudulent statements of fact and were dead letters to all intents and purposes over a decade ago.[172] The postal laws have not been very helpful.[173] That these statutes are ineffective is indicated by the very tide of legislation covering the advertising of specific articles.[174] It is significant that most of this supplemental legislation deals with food and drug products.[175]

The prohibition of false advertising in channels of interstate commerce is clearly within the federal power to regulate such commerce and may be exercised unless balked by intrusion of other constitutional law objections. Whether Congress can also restrain advertising appearing in intra-state media when the advertising induces the sale of goods across state lines (as provided in the bill) is a question which will be discussed in connection with the adulteration provisions of the bill. For the present, it will be assumed that the commerce clause extends to such advertising and that the Fifth Amendment represents the sole hurdle. In an opinion breathing sentiment rather than legal citation or logic, the Supreme Court has upheld a statute making it a misdemeanor to sell, expose for sale, or possess for sale any article of merchandise upon which there was placed for purposes of advertisement a representation of the flag of the United States.[176] The Court did not seem to pass on the point of the validity of the statute as applied to articles upon which the representation of the flag had been placed prior to the statute.[177] The Court has held that under the police power a state may validly regulate advertising connected with the sale of tobacco[178] and has sustained as valid as against the test of due process a city ordinance prohibit-

[169] Raladam Co. v. F. T. C., 42 F. (2d) 430 (C. C. A. 6th, 1930), *aff'd*, 283 U. S. 643, 51 Sup. Ct. 587 (1931). On this aspect of advertising control, see Handler, *Jurisdiction of Federal Trade Commission over False Advertising* (1931) 31 COL. L. REV. 526; Note (1931) 40 YALE L. J. 617; Note, *supra* note 102.

[170] For a collection of the Printers' Ink statutes, see Note (1927) 36 YALE L. J. 1155.

[171] See Handler, *supra* note 154, at 32 *et seq.*; Note (1931) 40 YALE L. J. 617, 621.

[172] See Cramp, *Truth in Advertising Drug Products* (1920) 10 AM. J. PUB. HEALTH 783, 788. Expenditures for advertising by companies in the food field run into the millions. See FOOD FIELD REPORTER, Nov. 6, 1933, at 24. For the year 1929, about $1,782,000,000 was spent in advertising to the consumer. Lynd, *The People as Consumers*, 2 RECENT SOCIAL TRENDS (1932), 857, 871.

[173] See Handler, *supra* note 154, at 30.

[174] See Note (1930) 43 HARV. L. REV. 945.

[175] *Id.* at 947.

[176] Halter v. Nebraska, 205 U. S. 34, 27 Sup. Ct. 419 (1907). *Contra:* Ruhstrat v. People, 185 Ill. 133, 57 N. E. 41 (1900).

[177] Such a statute was declared invalid as to articles on which the representation had been placed before passage of the statute. People *ex rel.* McPike v. Van De Carr, 178 N. Y. 425, 70 N. E. 965 (1904).

[178] See Packer Corp. v. Utah, 285 U. S. 105, 108, 52 Sup. Ct. 273, 274 (1932), (1932) 5 SO. CALIF. L. REV. 326.

ing advertising trucks.[179] In the state courts, ordinances prohibiting the unlicensed distribution of circulars on public highways[180] and the sale of periodicals with horse racing tips have survived judicial scrutiny.[181] A statute forbidding the distribution of medicinal preparations from house to house is proper.[182] More closely, it has been held that a lawyer can be denied the right to advertise for business in divorce litigation even though he so advertised and was admitted to the bar before the passage of the statute[183] and a number of decisions sustain statutes providing that a state board shall have the power to revoke the license of physicians and osteopaths who advertise "relating to venereal diseases or other matter of any obscene or offensive nature derogatory of good morals."[184] On the other hand, a statute revoking a physician's license for advertising which contains "grossly improbable statements" has been held too indefinite.[185] A statute authorizing revocation for "causing the publication and circulation of an advertisement relative to any disease of the sexual organs" has met a similar fate on the ground that the court was given no guide as to the meaning of "any disease of the sexual organs,"[186] an objection which may be obviated by the power which the present bill gives to the Secretary of Agriculture to issue explanatory regulations.[187] The Congressional declaration that self-medication for the thirty-six diseases is dangerous and that such advertisements are patently contrary to the interests of public health is not binding upon the court,[188] and thus will be subject to judicial review. Where the danger of self-medication is clear or where the matter is arguable, due process should not hinder the sweep of the Congressional prohibition of the false advertising.[189]

ADULTERATION UNDER THE ACT

The present Act gives the consumer somewhat better protection in the field of adulteration. As used in the Act and in judicial decision, "adulteration" has two aspects, an economic and a hygienic. The first consists in the complete or partial

[179] Fifth Avenue Coach Co. v. New York, 221 U. S. 467, 31 Sup. Ct. 709 (1911). *Cf.* Cusack Co. v. Chicago, 242 U. S. 526, 37 Sup. Ct. 190 (1917)

[180] Almassi v. City of Newark, 150 Atl. 217 (N. J. C. P. 1930), (1930) 5 TEMPLE L. Q. 150.

[181] Solomon v. City of Cleveland, 26 Oh. App. 19, 159 N. E. 121 (1926), cause dismissed in 116 Ohio St. 739, 158 N. E. 8 (1927).

[182] Ayers v. State, 178 Ind. 453, 99 N. E. 730 (1912).

[183] State v. Giantvalley, 123 Minn. 227, 143 N. W. 780 (1913).

[184] Glass v. Board of Medical Examiners, 50 Cal. App. 389, 195 Pac. 73 (1920); Kennedy v. State Board, 145 Mich. 241, 108 N. W. 730 (1906); State Board v. Macy, 92 Wash. 614, 159 Pac. 801 (1916); Laughney v. Maybury, 145 Wash. 146, 259 Pac. 17 (1927); Note (1928) 54 A. L. R. 400.

[185] Hewitt v. Board of Medical Examiners, 148 Cal. 590, 84 Pac. 39 (1906).

[186] Chenoweth v. State Board, 57 Colo. 74, 141 Pac. 132 (1913). *Contra:* State v. Hollinshead, 77 Ore. 473, 151 Pac. 710 (1915). But *cf.* cases cited note 184 *supra.*

[187] BILL, §23 (a). But see *infra* note 267.

[188] See Block v. Hirsh, 256 U. S. 135, 155, 41 Sup. Ct. 458, 459 (1921); People v. Nebbia, 262 N. Y. 259, 186 N. E. 694 (1933) *cert.* granted 54 Sup. Ct. 104.

[189] See Heath & Milligan Co. v. Worst, *supra* note 123, at 354, 28 Sup. Ct. 114, at 119; and the result achieved in Hebe Co. v. Shaw, *supra* note 4. But see Brown, *Legislation for Health and Safety* (1929) 42 HARV. L. REV. 866, 878 (queries if Congress can entirely prohibit proprietary medicines in view of Weaver v. Palmer Bros., 270 U. S. 402, 46 Sup. Ct. 320 (1926)).

substitution of a less valuable though possibly equally wholesome article,[190] the abstraction wholly or partially of any valuable constituent, the addition of some substance by mixing and packing which will affect strength or quality,[191] or in mixing, coloring, powdering, coating or staining a food product in a manner whereby damage or inferiority is concealed.[192] The second involves the addition of a poisonous or deleterious ingredient potentially rendering the article injurious to health,[193] or the shipment of foods which are in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance,[194] or of a diseased animal or one that has died otherwise than by slaughter.[195]

Where the provisions relating to economic adulteration are concerned, no injury to the health of the consumer need be threatened.[196] If, as in the case of confectionery, the Act mentions specific adulterants as talc or terra alba, their presence by mere chemical trace is enough to condemn the product.[197] And since the Act specifically provides that the standards of the United States Pharmacopoeia or National Formulary shall obtain for drugs, deviation from those standards is violative unless the drug package is specially labeled to indicate the deviation.[198] If a product's normal strength be diluted[199] or if the housewife fail to find an ingredient ordinarily present,[200] adulteration exists. Nor is a trade understanding a defense, unless shared in by the average consumer.[201] Also, even if a product may commonly attain a degree of impurity in its natural state, no warrant to the designing seller is given

[190] *Cf.* ACT, §7 (Food, 1, 2, 3).

[191] *Cf.* the general provisions in Section 7 as to the article falling below professed standard or quality, and the subsection dealing with confectionery.

[192] *Cf.* ACT, §7 (Food, 4).

[193] *Cf.* ACT, §7 (Confectionery) and §7 (Food, 5). The latter makes certain exceptions for preservatives where directions are given for their removal prior to consumption.

[194] *Cf.* ACT, §7 (Food, 6).

[195] *Id.*

[196] U. S. v. Boeckel & Co., 221 Fed. 885 (C. C. A. 1st, 1915).

[197] U. S. v. Boeckel & Co., *supra* note 196. That only a chemical trace was involved in the case appears in the lower court decision. N. J. No. 1642 (D. Mass. 1914). The confectionery subsection, after enumerating terra alba, barytes, talc, and chrome yellow, adds "or other mineral substances." The doctrine of *ejusdem generis* has been applied to limit this last clause to minerals used to increase bulk and weight at the expense of quality. French Silver Dragée Co. v. U. S., 179 Fed. 824 (C. C. A. 2d, 1910). *Contra:* U. S. v. Oriental Dragée Co., N. J. No. 176 (D. N. J. 1909). But *ejusdem generis* does not govern the next confectionery clause, "or other ingredient deleterious or detrimental to health." U. S. v. Watson-Durand-Kasper Grocery Co., 251 Fed. 310 (D. Kan. 1917).

[198] *Cf.* ACT. §7 (Drugs). It is interesting to note that several state statutes except from the permissible deviations from the U. S. P. and N. F. standards the following: opium, iodine, peppermint, camphor, ginger, ethyl nitrit. N. J. COMP. STAT. (1910) 2565; PA. STAT. (1920) §9339; TENN. ANN. CODE (Shannon, 1932) §6583. Maine provides that deviations when made must be plainly stated "so as to be understood by the non-professional person." ME. REV. STAT. (1930) c. 41, §18. Several statutes insist on the standards of other pharmacopoeia (such as the English, French, German, American Homeopathic) if the drug be sold under a name not recognized in the United States Pharmacopoeia. HAWAII REV. LAWS (1925) c. 76, §995; N. Y. Cons. Laws (Cahill, 1930) c. 15, §1359; MASS. CUM. STAT. (1927) c. 94, §186; PA. STAT. (1921) §§9339, 9340.

[199] U. S. v. Frank, 189 Fed. 195 (S. D. Ohio, 1911); U. S. v. Griebler, N. J. No. 37 (E. D. Ill. 1908).

[200] For typical examples see THORNTON, THE LAW OF PURE FOOD AND DRUGS (1912) §§127 (cream ale), 131 (apple jelly), 133 (berry preserves), 153 (custard).

[201] Wood Mfg. Co. v. U. S., 292 Fed. 133 (C. C. A. 8th, 1923).

artifically to introduce that degree of debasement.[202] The standards to be observed are determined by the courts in most instances;[203] the rulings of the Department of Agriculture are advisory only.

Fortunately for hygienic protection, a food need not be actually harmful at the time of seizure. It is enough if it will become injurious in a reasonable time.[204] No human intervention is necessary; if the food is naturally putrid or accidentally develops to be such, its shipment constitutes an offense.[205] Not only foods but substances entering into the composition of more complex food products must pass the governmental test.[206]

On the other hand the adulteration provisions fail in several respects to protect the consumer. Difficulties begin to arise when the law seeks to reach artificially compounded food preparations and drink concoctions.[207] Since no standard of sweetness is fixed, adding glucose does not adulterate.[208] The addition of water in excess of the average moisture has been held not an adulteration.[209] If, by the consumer's good fortune, the distinctive trade name actually mentions an ingredient, the food or drink must have it unless the defendant proves that no one expects its presence.[210] But if the manufacturer adroitly avoids mentioning what product is imitated by his own, gives his product a fanciful name such as "Banquet Spread" with no reference to an ingredient, and does not sell his product for the imitated

[202] U. S. v. 154 Sacks, Oats, 283 Fed. 985 (W. D. Va. 1922).

[203] On the need of standards, see REP. SEC. AGR. (1913) 18; *id.* (1916) 36; CHASE & SCHLINK, *op. cit. supra* note 56, at 64, 197-217. For standards as provided in the present Act, *cf.* 42 STAT. 1500 (1923), 21 U. S. C. A. §6; 46 STAT. 1019 (1930), 21 U. S. C. A. §10 (5) (Supp. 1929).

[204] U. S. v. 462 Boxes, Oranges, 249 Fed. 505 (D. Colo. 1917); U. S. v. 200 Cases, Canned Salmon, 289 Fed. 157 (S. D. Tex. 1923); Anderson & Co. v. U. S., 284 Fed. 542 (C. C. A. 9th, 1922). The Government need not prove that the article of food because of its adulteration *must* affect public health; if the product *may* injure any group, old, young, well, sick, and in any culinary form, it is adulterated. See U. S. v. Lexington Mill & Elevator Co., 232 U. S. 399, 411, 34 Sup. Ct. 337, 340 (1914). In England, similarly, the food need not be injurious to every person. Cullen v. McNair, 24 T. L. R. 692 (1908). But see Crawford, *Technical Problems in Food and Drug Law Enforcement, supra* p. 37.

[205] Dade v. U. S., 40 App. D. C. 94 (1913); *cert.* denied, 229 U. S. 610, 33 Sup. Ct. 771 (1913) (colon bacilli in milk); Galt v. U. S., 39 App. D. C. 470 (1913) (worms in flour); U. S. v. Sprague, 208 Fed. 419 (E. D. N. Y. 1913) (diseased oysters); U. S. v. 13 Crates, Frozen Eggs, *supra* note 11 (decomposed eggs). On departmental definitions of immaturity in certain fruits, see REG. ANN. 144, 164. An argument that the Act was invalid as excluding from interstate commerce all fish and meat as technically decomposed was ruled out as specious. Anderson & Co. v. U. S., *supra* note 204, at 544.

[206] Royal Baking Powder Co. v. Emerson, 270 Fed. 429, 434 (C. C. A. 8th, 1920), app. dismissed, 260 U. S. 752, 43 Sup. Ct. 166 (1922). In making inspection for adulteration, the Government is not limited to the standards of its own bulletins and circulars, nor to tests previously known to the scientific world. U. S. v. 100 Barrels, Vinegar, 188 Fed. 471 (D. Minn. 1911); Knapp v. Callaway, 52 F. (2d) 476 (S. D. N. Y. 1931). Reg. 4 is concerned with describing the ordinary methods of analysis. For the scientific problems involved in the testing of adulteration, see WINTON, THE MICROSCOPY OF VEGETABLE FOODS (1916); LEACH, FOOD INSPECTION AND ANALYSIS (4th ed. 1920). On tests used by the Department, see Howard, *Decomposition and Its Microscopical Detection in Some Food Products* (1911) YEARBOOK, DEPT. AGR. 297.

[207] *Cf.* U. S. v. Auerbach & Sons, N. J. No. 1803 (C. C. S. D. N. Y. 1912) ("Milk chocolate" may contain wheat starch); U. S. v. 150 Cases, Fruit Puddine, *supra* note 34.

[208] Washburn & Co. v. U. S., 224 Fed. 395 (C. C. A. 1st, 1915).

[209] U. S. v. 800 Sacks, Barley Mixed Oats, 64 F. (2d) 678 (C. C. A. 5th, 1933).

[210] U. S. v. Coca Cola Co., *supra* note 47.

product, in relation to what is it to be deemed inferior?[211] The compound may also most mildly suggest one of several ingredients, yet there is no adulteration though the percentage of the barely suggested ingredient becomes absurdly high.[212] Moreover, in view of the "Bleached-Flour" decision,[213] all kinds of technical poisons may be added to foods without legal condemnation unless the amount of the added substances is such that the food is harmful to health.[214] The poison must be "added"; foodstuffs poisonous in their natural condition (and not through putrid animal or vegetable substances) may pass to the consumer unchallenged by the Act. Similarly, drugs which are harmful to health under the conditions of use as presented by the vendor are exempt unless otherwise adulterated. The highly technical question of toxicity is submitted to a court and jury with frequently bizarre results. In addition, the law does not reckon with the devastating effects of cumulative injection. Again, as with misbranding, worthless cosmetics and anti-fat cures are not reached by the adulteration provisions of the Act.[215] Recently, the international coöperation afforded by the Act's restrictions as to adulterated foodstuff exports[216] has been confined to its literal scope of "preparation" and "packing" to meet the foreign law, and does not protect the foreign consumer from the dumping of "naturally" filthy and decayed products.[217]

ADULTERATION UNDER THE BILL

The bill is designed to take advantage of the retrospective wisdom which the decades have brought since 1906. In the field of economic adulteration, the bill retains much of the existing law.[218] Instead, however, of listing several operations by which damage or inferiority is concealed, the bill lays down a denunciation of such concealment in any matter.[219] The mixing and packing clause has similarly been changed so as to protect the consumer from deceptions as to bulk,[220] and drugs, for the first time, are brought within the mixing and packing and substitution of constituent provisions.[221]

[211] *Cf.* U. S. v. One Car Load, Corno Horse & Mule Feed, *supra* note 35, and the result achieved in U. S. v. Ten Cases, Bred Spred, *supra* note 65.

[212] U. S. v. One Car Load, Corno Horse & Mule Feed, *supra* note 35 *(semble)*.

[213] U. S. v. Lexington Mill & Elevator Co., *supra* note 204.

[214] See Wood Mfg. Co. v. U. S., *supra* note 46, at 86. The famous struggle within the Department of Agriculture concerning the Bureau of Chemistry occurred over precisely this matter. *Cf.* WILEY, THE HISTORY OF A CRIME AGAINST THE FOOD LAW (1929).

[215] See note 71, *supra; "Lesser Slim Figure Bath"* (1929) 92 AM. MED. ASSN. J. 492.

[216] ACT, §2.

[217] U. S. v. Catz American Co., 53 F. (2d) 425 (C. C. A. 9th, 1931).

[218] The bill emphasizes the two types of adulteration by listing them in separate paragraphs. *Cf.* BILL, §3 (a) with §3 (b). In addition to the changes listed in the text, the bill makes several other changes, the most important of which is its control of coal tar. *Cf.* BILL, §3 (d). The bill does not restrict filth, putridness, and decomposition to animal and vegetable substances. *Id.* §3 (a) (3).

[219] BILL, §3 (b) (3).

[220] *Cf.* BILL, §3 (b) (4) with Act, §7 (Food, 1). The language of the bill is sufficiently broad so that it will strike at false top packing.

[221] BILL, §4 (d). It is difficult to understand, however, why the bill is so considerably narrower in the field of economic adulteration of drugs than in that relating to foods. *Cf.* BILL, §4 (d) with §3 (b).

The chief contribution of the bill relates to hygienic adulteration. A food is to be deemed adulterated "if it is or may be dangerous to health"[222] and a drug likewise shall be adulterated "if it is or may be dangerous to health under the conditions of use prescribed in the labeling thereof."[223] The introduction of terminology dealing with foods and drugs potentially dangerous to health but verbalizes the present law with respect to added deleterious ingredients.[224] What is important is the extension of this aspect of the present law to cover all forms of adulteration and the emphasis on the result rather than on the manner in which the adulteration has been accomplished. Whether the bill adequately strikes food products dangerous to health through their cumulative ingestion is not certain,[225] though such danger is often most serious, and the provision noted is whipping in that direction. The "Bleached Flour" decision is avoided by providing that the Secretary may fix tolerances for poisonous ingredients.[226] The test as to the presence of technical poisons would henceforth not depend on whether the poison is present in such proportion as actively to threaten the consumer's life. The Government would no longer permit the fruit grower to play unduly with poisonous sprays but would establish a border zone, trespass beyond which would bring the federal penalties. Food is also to be adulterated if packed in containers composed of poisonous or deleterious substances which may by contamination render the contents dangerous to health.[227] Drugs must more closely conform to the United States Pharmacopoeia or National Formulary,[228] although deviation is still permitted if noted on the label. Cosmetics are

[222] *Id.* §3 (a) (1). The language is designed to hit the foods containing "natural" poisons.

[223] *Id.* §4 (a).

[224] See note 204, *supra.*

[225] The cumulative ingestion problem seems noted only in the section dealing with tolerances of added poisons. BILL, §10 (a). Moreover, the very expression of the cumulative test in this section will tend to negate its application in the other types of adulteration.

[226] *Id.* The bill omits completely the Act's permission of such ingredients for preservatives, a permission given only if directions for removal are given. *Cf.* ACT, §7 (Food, 5). In absence of a statutory exception, a substance is an adulterant though its purpose and use are preservative. People v. Bowen, 182 N. Y. 1, 74 N. E. 489 (1905); Commonwealth v. Gordon, 159 Mass. 8, 33 N. E. 709 (1893); State v. Schlenker, 112 Iowa 642, 84 N. W. 698 (1900).

[227] *Id.* §3 (a) (6). There is no analogous provision for drugs. The test given by the Bill contrasts with its general emphasis on result rather than on method of adulteration; in this instance of the container the Bill regards the composition of the container too closely and does not strike at adulteration gained through interaction with containers howsoever occasioned. *Cf.* the somewhat broader language of state statutes dealing with this question. VA. CODE (Michie, 1930) §1181 (7). KEN. REV. STAT. (Carroll, 1930) §2060a-2 makes food misbranded if the label fails to disclose the length of time of packing where retention unduly prolonged would tend to render the food unwholesome.

[228] BILL, §4 (b). The bill recognizes the supplements official at the time the drug is introduced into interstate commerce. Under the Act the standard of these volumes became operative when the drug was "sold" under the names recognized in the Pharmacopoeia and Formulary. ACT, §7 (Drugs, 1). Under the Bill, the drug's name need only be the same or simulative of the name of drugs in those volumes. Under the Act, the drug had to meet the U. S. P. or N. F. standards of strength, quality, and purity. The bill adds that the drug must meet the U. S. P. or N. F. "definition, formula and description." The drug must meet the standards of the U. S. P. or N. F. in accord with the tests or methods of assay given in these volumes, or those of the Secretary if he finds the former insufficient. Note that this does not give the Secretary power to fix drug standards; he is merely given power to prescribe tests for the determination of the U. S. P. or N. F. standard. *Cf.* a similar power given to the Canadian Governor in Council. CAN. REV. STAT. (1917) c. 76, §6 (4). But the Canadian Governor may prescribe drug standards

deemed adulterated if presently or potentially injurious to the user under the conditions prescribed in the labeling or under such conditions of use as are customary.[229] In addition, cosmetics must not bear or contain poisonous or deleterious ingredients prohibited, or in excess of the limits of tolerance to be established.[230] Instead of the prior detailed provision as to what confectionery might not contain, the present confectionery clause reads simply that confectionery may not bear or contain any alcohol, resinous glaze, or non-nutritive substance.[231] The revision seems primarily directed at the metallic tokens and prizes which are too often packed inside candy boxes or placed even within the candy itself.[232]

But included in Section 3 of the bill, a section dealing with the adulteration of foods, is a clause which though innocent at first reading represents, with the exception of the National Recovery Act and attendant legislation, one of the most powerful thrusts of the federal power into what has hitherto been a realm of affairs solely the province of the states and which has been considered in the main immune from federal intervention. Section 3(a) (4) provides that a food is to be deemed adulterated "if it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth."[233] This is plainly an indirect method of controlling the conditions of packing and manufacture. The bill is not satisfied with this indirect control. Under the present Act, the Department's lack of power to inspect places where food is prepared has hindered its reaching certain types of adulteration which elude chemical and bacteriological tests.[234] Section 12 (which if read closely will be found to deal only with this situation) provides that in such cases, the Secretary of Agriculture after notice and hearing may make such regulations governing the conditions of manufacture, processing, or packing as he deems necessary to protect the public health, and may require the manufacturers, processors, and packers of such classes of articles to hold a permit conditioned on compliance with such regulations. The section applies to drugs and cosmetics as well as foods,

in addition to tests. *Id.* §6 (3). On the constitutionality of prescribing the method of determining a standard, see L. R. A. 1916 E379. In Savage v. Jones, *supra* note 4, the Indiana statute before the Court provided that constituents were to be determined by the methods recommended by the Association of Official Agricultural Chemists of the United States. The question of its constitutionality on this score was not considered.

[229] BILL, §5 (a).

[230] *Id.* §5 (b).

[231] *Id.* §3 (c). Coloring and flavoring are expressly excepted and may be present though non-nutritive. In the following state statutes, substances permitted by the federal law are prohibited in confectionery: ALA. ANN. CODE (Michie, 1928) §4402 (burnt umber); ILL. REV. STAT. (Cahill, 1929) c. 56 b, §8 (paraffin); NEB. COMP. STAT. (1929) §81-903 (paraffin); N. D. COMP. LAWS (1913) §2280 (aniline dyes); UTAH COMP. LAWS (1917) §1927 (2) (paraffine). Maryland specifically permits "salt" in confectionery. MD. ANN. CODE (Bagby, 1924) art. 43, §191.

[232] *Cf.* NEB. COMP. STAT. (1929) §81-903.

[233] The bill as phrased does not seem to include unsanitary conditions of transportation. Those state food and drug laws which have advanced to control the surrounding conditions are couched in more sweeping language. *Cf.* ME. REV. STAT. (1930) c. 41, §18 (7); PA. STAT. (1920) §61; N. Y. CONS. LAWS (Cahill, 1930) c. 1, §199 (8); TEX. PEN. CODE (1928) art. 707. For the validity of an analogous provision, see People v. Bowen, 182 N. Y. 1, 74 N. E. 489 (1905).

[234] See Crawford, *supra* p. 38.

and the introduction into interstate commerce of any food, drug, or cosmetic is forbidden if the manufacturer, processor, or packer does not hold a valid and subsisting permit when so required. Further, in order to aid in enforcement, officers or employees designated by the Secretary, after first obtaining permission of the owner, operator, or custodian thereof are authorized to enter and inspect any factory, warehouse, or establishment in which food, drugs, or cosmetics, are manufactured, processed or held for shipment in interstate commerce or are held after the interstate shipment.[235] The permission required of the owner, operator and custodian is illusory; if they do not grant the permission, an injunction may issue denying articles coming from such factories, warehouses, vehicles, etc., the right to enter into the interstate commerce or to be delivered after their receipt in interstate commerce.[236]

These provisions abut very closely upon the theoretical line separating state and federal powers. While not as far-reaching as the recent emergency legislation enacted by Congress, they raise similar questions. Formulae to sustain this extension of control are not lacking.[237] It must be remembered that the measures taken are designed merely to protect the stream of interstate commerce. No jurisdiction is assumed over articles which do not at some time cross state lines. The difficulties of the *Child Labor* decision[238] are only apparent; the Court itself in that decision distinguished its food and drug law precedents by the dictum that the goods made by child labor were in themselves harmless.[239] Moreover, the Court has nominated adulterated foods and drugs "illicit articles" and has expressly refused to apply to them the rule marking the line between the exercise of federal and state power over articles of "legitimate commerce."[240] If Congress can provide for the inspection of

[235] BILL, §13 (a). Similar powers have been granted the Department in analogous statutes. *Cf.* Meat Inspection Law, 34 STAT. 1260, 1262 (1907), 21 U. S. C. A. §§71, 76; Biologic Products Law, 37 STAT. 833 (1913), 21 U. S. C. A. §157; Import Milk Act, 44 STAT. 1101, 1102 (1927), 21 U. S. C. A. §143; Adulterated Butter Act, 32 STAT. 196 (1902), 26 U. S. C. A. §578. The bill's provision does not appear to violate the provisions of the Fourth and Fifth Amendments. See cases collected in (1931) 15 MINN. L. REV. 481; (1931) 25 ILL. L. REV. 937. But *cf.* U. S. v. Mulligan, 268 Fed. 893 (N. D. N. Y. 1920); Sullivan v. Brawner, 237 Ky. 730, 36 S. W. (2d) 364 (1931). The requirement of an ordinance that samples be given food inspectors without compensation has been held a valid exercise of police power. State v. Dupaquier, 46 LA. ANN. 577, 15 So. 502 (1894); St. Louis v. Liessing, 190 Mo. 464, 89 S. W. 611 (1905); Com'r v. Carter, 132 Mass. 12 (1882). Possibly, even in absence of statutory authority, the taking of the sample without payment therefor comes within the rule of *de minimis*. *Cf.* U. S. v. B. & M. External Remedy, 36 F. (2d) 53 (S. D. N. Y. 1929). Several of the state food and drug laws have more sweeping inspection provisions than that of the bill. IDAHO, COMP. STAT (1919) §1675; ILL. REV. STAT. (1929) c. 56 b, §2; KANS. REV. STAT. (1923) §65-612; MINN. STAT. (1927) §3798.

[236] BILL, §13 (b).

[237] See Dickinson, *Major Issues Presented by the NIRA* (1933) 33 COL. L. REV. 1095, 1099, and the discussion of the commerce clause in Handler, *The National Industrial Recovery Act* (1933) 19, AM. B. ASSN. J. 440. In Canada, the Governor in Council may license manufacturers preparing a list of named drugs. CAN. REV. STAT. (1927) c. 76, 56 (3-c).

[238] Hammer v. Dagenhart, 247 U. S. 251, 38 Sup. Ct. 529 (1918).

[239] *Id.* at 270-272, 38 Sup. Ct. at 530-531.

[240] Hipolite Egg Case, *supra* note 8, at 57, 31 Sup. Ct. at 367. For an analysis of this doctrine of "illicit" articles, see Corwin, *Congress's Power to Prohibit Commerce* (1933) 18 CORN. L. Q., 477, 479.

such goods after they have come to rest and have been commingled with local products,[241] it may with equal propriety cause the goods to be inspected before their start on the interstate journey[242]—at least in those cases when such inspection possesses sole efficacy.

The bill's advertising control suggests similar constitutional questions but is easier to sustain because limited to transmission of intelligence across state lines and the solicitation of interstate sales.[243] *Weeks v. United States*[244] held that Congress could prevent the interstate shipment of foods orally offered under the name of other foods. The converse corollary that Congress may control the representations concerning goods moving in the stream seems evident. The power of Congress should not depend on the mere location of the statement affecting the article.[245]

REGULATIONS UNDER THE ACT AND BILL

No review of the substantive provisions of the bill would be complete without attention to the wide powers which it gives to the Secretary of Agriculture. Under the present Act the power to make rules and regulations for the carrying out of the provisions of the Act is lodged in a triumvirate consisting of the Secretaries of the Treasury, Agriculture, and Commerce.[246] The Act contents itself with this general delegation of power; with the exception of the tolerances and exemptions as to small packages under the Gould Amendment,[247] it fails to establish any directive standards for the exercise of the power. The bill contrasts. It is replete with reference to the executive power which, with the exception of import regulations shared with the Secretary of the Treasury,[248] is vested solely in the Secretary of Agricul-

[241] Hipolite Egg Case, *supra* note 8; see McDermott v. Wisconsin, *supra* note 4, at 135, 33 Sup. Ct. at 436 ("Congress may determine for itself the character of the means necessary to make its purpose effectual in preventing the shipment in interstate commerce of articles of a harmful character, and to this end may provide the means of inspection, examination and seizure necessary to enforce the prohibitions of the act. . . . The opportunity for inspection en route may be very inadequate."); Foote v. Maryland, 232 U. S. 494, 34 Sup. Ct. 337 (1914).

[242] See the conclusion drawn by Holmes, J., from the Hipolite Egg Case and Weeks v. United States: "It does not matter whether the supposed evil precedes or follows the transportation. It is enough that in the opinion of Congress the transportation encourages the end." This was expressed in his dissenting opinion, Hammer v. Dagenhart, *supra* note 238, at 279, 38 Sup. Ct. at 534, but as indicated in the text, the distinction there taken by the majority is inapplicable to foods packed under unsanitary conditions or conditions making detection of adulteration difficult. In Pittsburgh Melting Co. v. Totten, 248 U. S. 1, 8, 39 Sup. Ct. 3, 4, (1918) the court said of the Meat Inspection Statute "The enactment of the statute was within the power of Congress in order to prevent interstate and foreign shipment of impure or adulterated meat-food products." *Cf.* also U. S. v. Cudahy Packing Co., 243 Fed. 441 (D. Conn. 1917). The Meat Inspection statute was apparently unchallenged in Brougham v. Blanton Mfg. Co., 249 U. S. 495, 39 Sup. Ct. 363 (1919).

[243] Such solicitation is part of interstate commerce. See Robbins v. Shelby Taxing District, 120 U. S. 489, 497, 7 Sup. Ct. 592, 596 (1887); Crenshaw v. Arkansas, 227 U. S. 389, 396, 33 Sup. Ct. 294 (1913); Note (1927) 48 A. L. R. 563.

[244] *Supra* note 5.

[245] See Seven Cases, Eckman's Alterative v. U. S., *supra* note 29, at 515, 36 Sup. Ct. at 192.

[246] ACT, §3.

[247] *Supra* note 26.

[248] *Cf.* Section 23 (a) of the bill with the subject matter of Section 20.

ture.[249] Under the bill, he has power, *inter alia,* to make regulations as to coal-tars and certify batches of coal-tars;[250] to adopt tests and methods of assay whenever he finds those of the United States Pharmacopoeia or National Formulary insufficient;[251] to prescribe the manner and form of statements on drugs which deviate from the standards set in those volumes;[252] to fix, establish, and promulgate definitions of identity and standards of quality and fill of container for any food;[253] to prohibit added poisons or establish tolerances for such poisons;[254] to regulate factories manufacturing classes of foods, drugs, and cosmetics injurious and difficult of detection by analysis of the product itself;[255] to exempt classes of canned goods when being transported to an establishment for labeling;[256] to require a statement of standard of quality on the label;[257] to fix the statement of the quantity and proportion of hypnotic substances, alcohols, and chloroform;[258] to exempt certain drugs from label requirement as to statement of condition of use;[259] to authorize advertisements for self-medication[260] and to add new diseases to the self-medication list.[261] In the cases of foods for which no definition of identity has been provided and of drugs not mentioned in or simulative in name to those in the United States Pharmacopoeia and National Formulary, he has virtually a *carte blanche* respecting statements on the label.[262] The promulgation of only some of these regulations must be preceded by a notice and hearing. Of these, the most important are those regulations establishing definitions of identity, standards of quality, and fill of container for any food. Here the necessity for the prior notice and hearing may become factually most burdensome and unduly delay the enforcement of the law. The notice and hearing do not appear to be required because of considerations of constitutional law; the Constitution merely demands that the regulation of the administrative officer shall not be arbitrary and would hardly seem to insist on the formal hearings which the bill so frequently contemplates.[263]

The delegation of the standard making and other powers to the Secretary seems well within constitutional bounds. The distributing clause is not part of the Federal Constitution,[264] and in theory, so long as Congress indicates a "primary" standard, the Secretary merely fills in the details.[265] Actually, the "primary" standard need

[249] *Id.* §23 (a).
[250] *Id.* §10 (b). *Cf. Id.* 3 (d).
[251] *Id.* §4 (b). See *supra* note 228.
[252] *Id.*
[253] *Id.* §11.
[254] *Id.* §10 (a).
[255] *Id.* §12 (a).
[256] *Id.* §6 (b).
[257] *Id.* §7 (e).
[258] *Id.* §8 (b) (c).
[259] *Id.* §8 (d).
[260] *Id.* §9 (c).
[261] *Id.*
[262] *Id.* §7 (f).

[263] Buttfield v. Stranahan, 192 U. S. 470 (1904); *cf.* Norwegian Nitrogen Products Co. v. U. S., 288 U. S. 294, 53 Sup. Ct. 350 (1933); Bi-Metallic Investment Co. v. Colorado Board, 239 U. S. 441, 36 Sup. Ct. 141. The rule seems to be that an administrative order which, as distinguished from an administrative regulation, operates by way of individual discrimination need not be preceded by notice and hearing. See Note (1931) 80 U. OF PA. L. REV. 96.

[264] See Note (1922) 35 HARV. L. REV. 450, 452; Powell, *Separation of Powers: Administrative Exercise of Legislative and Judicial Power* (1912) 27 POL. SC. Q. 9, 215, 216-217.

[265] See Note, *supra* note 264.

only be the enunciation of broad policies.[266] The regulations which the Secretary makes cannot add to the law,[267] and there is some indication that the definitions of identity and standards of quality and fill must be also sufficiently comprehensive as to permit the sale of all the usual classes of products without unnecessary interference.[268]

SANCTIONS UNDER THE ACT

The present Act gives the Government two chief weapons, criminal prosecution of the violator under Section two and forfeiture of the outlawed goods under Section ten. The violation of the Act is a federal misdemeanor. A first offense carries a fine not exceeding two hundred dollars, and conviction for each subsequent offense not exceeding three hundred dollars, or imprisonment, not exceeding one year, or both in the discretion of the court.[269] A defendant who ships several kinds of articles in one shipment can be separately fined for each,[270] but cannot be subjected to a multiple fine if the shipment consists of units of the same article, though in separate packages.[271] For the criminal violation no *mens rea* is needed except in cases involving "false and fraudulent" therapeutic claims. The Act has substituted for the common law principle of *"caveat emptor"* the stern principle of *"caveat venditor,"* so that the receiving seller or shipper violates the law the moment he contaminates the stream of interstate commerce and his intentions, his care, his inspection, his knowledge or lack of knowledge of the fraud or adulteration are all immaterial[272] save in the solitary instance of statements concerning the therapeutic value of drugs. The exact methods for investigation, conviction and forfeiture are detailed and fairly complex.[273] The amazingly high number of pleas of guilty[274] and the frequent

[266] See Note (1933) 31 MICH. L. REV. 786; Note (1929) 27 MICH. L. REV. 558; Note (1931) 19 CALIF. L. REV. 448.

[267] Lynch v. Tilden Co., 265 U. S. 315, 44 Sup. Ct. 488 (1924) (Regulation could not add "moisture" standard for adulterated butter); Waite v. Macy, 246 U. S. 606, 38 Sup. Ct. 395 (1918) (regulation cannot exclude tea having infinitesimal amount of innocuous coloring matter); see U. S. v. Antikamnia Co., *supra* note 25, at 666, 34 Sup. Ct. at 225; Hayes & Ruff, *supra* p. 20, n. 20. The Secretary's finding of fact is conclusive if fairly arrived at and if it have substantial evidence in support. Houston v. St. Louis Independent Packing Co., 249 U. S. 479, 39 Sup. Ct. 332 (1919). A violation of a food regulation is sufficient to support a criminal action. United States v. Grimaud, 220 U. S. 506, 31 Sup. Ct. 480 (1911). As to its sufficiency in a libel for seizure, *cf.* U. S. v. Antikamnia Chemical Co., *supra.*

[268] See the doctrines announced in Burns Baking Co. v. Bryan, 264 U. S. 504, 44 Sup. Ct. 412 (1924); Quaker Baking Co. v. Herring, 3 F. Supp. 118 (S. D. Ia. 1933); Holsum Baking Co. v. Green, 45 F. (2d) 238 (N. D. Ohio 1930); Morgan v. Nolan, 3 F. Supp. 143 (S. D. Ind. 1933); *In re* Mefferd, 110 Cal. App. 1, 292 Pac. 988 (1930); Marshall v. Dept. of Agriculture, 44 Idaho 440, 258 Pac. 171 (1927); Atlantic Refining Co. v. Trumbull, 43 F. (2d) 154 (D. Conn. 1930), Note (1930) 40 YALE L. J. 116. But *cf.* Waters-Pierce Oil Co. v. Deselms, 212 U. S. 159, 29 Sup. Ct. 270 (1909).

[269] ACT, §2.

[270] U. S. v. Direct Sales Co., 252 Fed. 882 (W. D. N. Y. 1918).

[271] U. S. v. Watson-Durand-Kaspar Grocery Co., *supra* note 197; see Andersen & Co. v. U. S., *supra* note 204, at 544.

[272] U. S. v. 36 Bottles, London Dry Gin, *supra* note 45; U. S. v. 267 Boxes, Macaroni, *supra* note 44; U. S. v. Sprague, 208 Fed. 419 (E. D. N. Y. 1913).

[273] See Hayes & Ruff, *supra* p. 25 *et seq.*

[274] The following chart was prepared by abstracting and then consolidating data from the schedules of business in the District and Circuit Courts in the annual reports of the Attorneys-General of the United States. The period covered is from the passage of the Act in 1906 through June 30, 1932.

summoning of the same offender before the courts indicates that many firms, immune as corporations from imprisonment,[275] regard the system of confiscation, suspension of sentence, and light fines[276] as a very moderate license charge for plying their trade. Goods released under bond have a way of surreptitiously reaching food and drug markets,[277] and by a continued series of changes in a label or formula, defendants avoid the effect of even successful prosecution.

The law has also received the support of indirect sanctions. Executory agreements under which adulterated foods move in interstate commerce may be breached with impunity,[278] and violation of the statute set up as a defense to actions brought for the purchase price of retained goods.[279] Where the consumer is injured because of his reliance on statements made on the label or package circulars, the violation of the Act takes the question of negligence away from the jury,[280] but it has been held

Civil Forfeiture (§10)	
Actions commenced	19,459
Judgments for U. S.	17,257
Judgments against U. S.	171
Dismissed or discontinued after payment or compromise	336*
Dismissed for other reasons	1,316
Amount of judgment for U. S.	$197,483.60
Amount realized on such judgments (including interest)	$200,772.69
Actions unaccounted for	12
Actions pending June 30, 1932	284

Criminal Prosecution (§§1, 2)	
Actions commenced	9,233
Convictions	7,354
Acquittals	136
Nolle prossed or discontinued	934†
Quashed on demurrer, etc.	143
Pleas of guilty	6,699
Trials by jury	510
Fines, penalties, etc.	$491,916.14
Amount realized on such fines, penalties, etc.	$469,191.25
Actions pending June 30, 1932	114

*Prior to 1911, 83 dismissals were reported without mention of reasons. These have not been included above.

†Prior to 1911, 88 cases were reported without differentiation as to nolprossed or quashed. These have not been included above.

[275] As far as the records indicate, in the whole history of enforcement of the Act, but two prison sentences have been imposed. One was remitted, and in the other (N. J. No. 9008) a poor foreigner was sentenced to a year in jail. Prison sentences are occasionally imposed in connection with the postal, prohibition, and customs violations which are incidentally disclosed. See note 56, *supra*. For successful use of an indictment for conspiracy to violate the statute, see Mitchell v. U. S., 229 Fed. 357 (C. C. A. 2d, 1916). The bill attempts to reach the corporate officers. BILL, §18. *Cf.* N. Y. LAWS 1909, c. 49 art. 11, as amended.

[276] See *supra* p. 109.

[277] See (1930) 117 OIL, PAINT AND DRUG REP. 117; Rusby, *The Fight for Pure Drugs* (1930) 7 PLAIN TALK 333. In the years 1919 to 1922, of 4,713 decrees of condemnation 1,202 were released under bond. REP. ATT'Y GEN. (1919) 84; *id.* (1920) 145; *id.* (1921) 106; *id.* (1922) 87.

[278] Trafton v. Davis, 110 Me. 318, 86 Atl. 179 (1913); Hopkins & Co. v. Silverman, 234 App. Div. 224, 254 N. Y. Supp. 724 (1932) (despite technical release by Government); *cf.* Barron County etc. Co. v. Niana Pure Food Co., 191 Wis. 635, 211 N. W. 764 (1927). But *cf.* McNeil & Higgins Co. v. Martin, 160 La. 443, 107 So. 299 (1926). North Dakota's food and drug law specifically provides that no action may be maintained on account of any sale or other contract made in violation of the food and drug law. N. D. COMP. LAWS ANN. (Supp. 1925) §2889a 15. In England, contracts are not generally affected by the Sale of Food and Drug Law. *Cf.* 18 & 19 GEO. V, c. 31, §33. See also on the private right of action for violation of a commodity standards law, Note (1931) 31 COL. L. REV. 872, 880.

[279] Digestive Ferments Co. v. Am. Chem. Laboratories, 80 Pa. Super. Ct. 373 (1923). The defense is not available where a defendant retains goods after being ordered to return them for relabeling. Makris v. Moore, 74 Utah 478, 280 Pac. 721 (1929). And *cf.* Walker v. Gateway Milling Co., *supra* note 38; Hall-Baker Grain Co. v. U. S., *supra* note 31. Several state food and drug laws have made the defense available as a statutory right. MINN. STAT. (Mason, 1927) §3801; N. H. PUB. LAWS (1926) c. 139, §11; ORE. CODE ANN. (1930) §41-225.

[280] Armour v. Wanamaker, 202 Fed. 423 (C. C. A. 3d, 1913).

that the shipping of a "naturally" adulterated product does not have similar force.[281] In accord with the general doctrine of "unclean hands," labels not meeting the requirements of the statute are not protected in suits for infringement of trade-mark,[282] nor can a violator recover under the Sherman Anti-Trust Act.[283] The Post Office and prohibition enforcement authorities have sometimes been able to give supplementary aid.[284] Reference has already been made to the power of the Federal Trade Commission to intervene where the violation crosses into the realm of "unfair competition."[285]

Entrapment is a defense to prosecutions under the Act.[286] The possession by a dealer of a valid guaranty, signed by a wholesaler, jobber, or other person residing in the United States, to the effect that the articles purchased are not adulterated or misbranded under the Act, is a defense, but the guarantor is liable for the penalties that would otherwise would attach to the dealer.[287]

SANCTIONS UNDER THE BILL

The bill strengthens the provision as to seizure and criminal penalties and adds the following weapons to the Government's arsenal: injunction, publicity, voluntary inspection system, and a right of private action. To the present method of seizure pursuant to a libel, the bill provides for an executive seizure by an order of a chief of station or other officer of the Food and Drug Administration founded on probable

[281] Armour & Co. v. Miller, 39 Ga. App. 228, 147 S. E. 184 (1929), Note (1930) 7 N. Y. U. L. Q. 738, 742. A proper label and guaranty under the Act will aid a defendant in an action brought for negligence. *Cf.* Bigelow v. Maine Cent. R. Co., 110 Me. 105, 85 Atl. 396 (1912); People v. Lang, 164 N. Y. Sup. 5 (1917). On the difficulties facing the plaintiff in actions brought for injury due to service of improper food, see Perkins, *Unwholesome Food* (1919) 5 IOWA L. BULL. II, 86, 96; Shoemaker, *Sales of Food by Restaurant Keeper* (1927) 12 CORN. L. Q. 535; (1927) 75 U. OF PA. L. REV. 676; (1928) 26 MICH. L. REV. 825.

[282] *Cf.* American Thermos Bottle Co. v. W. T. Grant Co., 282 Fed. 426 (C. C. A. 1st, 1922); See Handler, *supra* note 154, at 50, n. 79; HOPKINS, TRADE-MARKS (4th ed. 1924) §38; ROGERS, *op. cit. supra* note 66, at 123. A wholly technical violation of the Act will not estop the plaintiff. Bonnie & Co. v. Bonnie Bros., 160 Ky. 487, 169 S. W. 871 (1914). Apparent departmental sanction of the plaintiff's trade-mark through lack of prosecution will aid in an action to prevent registration of an infringing trade-mark. See Orange Crush Co. v. California Crushed Fruit Co., 297 Fed. 892, 894 (App. D. C. 1924). The Patent Office will refuse to register marks violating the Act. *Ex parte* Barclay & Barclay, 135 O. G. Pat. Off. 217 (1908); *cf.* Levy & Co. v. Uri, 31 App. D. C. 441 (1908).

[283] Proper v. Bene & Sons, 299 Fed. 863 (E. D. N. Y. 1924); see Note (1932) 32 COL. L. REV. 335.

[284] See REP. SEC. AGR. (1914) 167; Alsberg, *supra* note 56, at 213. But *cf.* Handler, *supra* note 154, at 32.

[285] *Supra* note 102.

[286] Where the initial shipment is procured by entrapment, an indictment will be dismissed in absence of evidence of other interstate shipments. U. S. v. Eman Mfg. Co., 271 Fed. 353 (D. Colo. 1920). But *cf.* U. S. v. 50 Barrels, Whiskey, 165 Fed. 966 (D. Md. 1908).

[287] ACT, §9. See Reg. 6. The guaranty defense is available only when relating to the identical article shipped and not when concerning only a constituent used in the manufacture of the article shipped. See U. S. v. Mayfield, 177 Fed. 765, 768 (N. D. Ala. 1910). It may be a "continuing" guaranty. Glaser, Kohn & Co. v. U. S., 224 Fed. 84 (C. C. A. 7th, 1915); see Reg. 6 (d). *Contra:* U. S. v. Scully Syrup Co., N. J. No. 2471 (N. D. Ill. 1913). But a guaranty given after prosecution has been instituted, though before conviction, brings no immunity. Steinhardt Bros. & Co. v. U. S., 191 Fed. 798 (C. C. A. 2d, 1911). The guaranty will probably protect a dealer from prosecutions arising out of his own subguaranty. 26 OP. ATT'Y GEN. (1908) 449. On the protection accorded a dealer under a state law because of a federal guaranty, see City of St. Louis v. Wortman, 213 Mo. 131, 146, 112 S. W. 520, 525 (1908).

cause to believe that the article to be seized is so adulterated as to be imminently dangerous to health.[288] This summary method of seizure does not apply at all to misbranded articles or to articles which have been economically adulterated. Its sole concern is to protect the public from foods, drugs, and cosmetics immediately dangerous to health. As such, the executive seizure seems to rest on a sound constitutional basis,[289] especially since a right of action is not denied against the officer who seizes articles in fact not so imminently dangerous. Indeed, the bill makes express provision that the amount recovered in such actions shall be provided for and paid out of appropriations for the administration of the law.[290] Release under bond after condemnation subsequent to the seizure becomes more clearly discretionary,[291] but the destruction of articles condemned because of failure of the manufacturer, processor, or packer to hold a valid permit if same be required of them, is not discretionary but mandatory.[292] The bill provides that the articles may be released for bringing into compliance with the law only if the compliance is effected under the supervision of an officer or employee designated by the Secretary of Agriculture and the expenses of the supervision paid by the party obtaining release of the article under bond.[293]

The criminal penalties are raised. A violation will now carry for the first offense a minimum fine of $100, a maximum fine of $1,000.[294] A first offense will also subject the violator to imprisonment for not more than one year as alternative or in addition to the fine. A second or subsequent offense will carry imprisonment for not more than two years, or a fine of not less than $500 nor more than $3,000, or both such imprisonment and fine. Although as indicated the bill removes even the present sole exception requiring *mens rea,* the bill's penalty section takes cognizance of the distinction between wilful and non-wilful violation of the law. Under the provisions of Section 17(c), in the case of wilful offense, the penalty is to be imprisonment for not less than six months nor more than three years, or a fine of not less than $1,000 nor more than $10,000, or both such imprisonment and fine. It is important to note that the bill thus provides for not inconsiderable minimum fines and in the case of wilful offender for the alternative of a minimum prison term of six months. Although constitutional,[295] these penalties are severe, and where the

[288] BILL, §16 (a). *Cf.* the very drastic seizure and forfeiture provisions of Oleomargarine Act, 24 STAT. 212 (1886), 26 U. S. C. A. §555; CAN. REV. STAT. (1927) c. 76, §30.

[289] North American Storage Co. v. Chicago, 211 U. S. 306, 29 Sup. Ct. 101 (1908) (no notice or hearing needed under Fourteenth Amendment prior to seizure).

[290] BILL, §16 (b).

[291] *Id.* §16 (d).

[292] *Id.* The discrimination seems justified in view of the character of the articles manufactured in such permit factories.

[293] *Id.*

[294] BILL, §17 (b).

[295] People v. Adams, 176 N. Y. 351, 68 N. E. 636 (1903), *aff'd,* 192 U. S. 585, 24 Sup. Ct. 372 (1904) (the point was not argued in the Supreme Court). The question of validity which has been raised is that of constitutional provisions forbidding unusual and cruel punishments. The maximum and minimum sentence is not uncommon in statutes providing for indeterminate sentences. See Note (1928) 18 J. CRIM.

offense is not wilful the severity may tend to lead either to acquittal or to a suspension of sentence. That the statutory crime carries prison sentences despite the absence of *mens rea,* is not unusual in the rapidly expanding field of "public welfare" offenses.[296] A recent historical survey indicates that in the field of food control the whole doctrine of crimes without *mens rea* arose and cross-pollinated.[297]

Section 19 of the bill declares both the repetitious introduction of adulterated or misbranded food, drugs, and cosmetics into interstate commerce and the repetitious dissemination of false advertising regarding such products to be public nuisances which may be enjoined at the suit of the government. To bring the injunctive restraint within the recognized heads of equity jurisdiction of the federal courts, the statute in addition to thus utilizing the nuisance formula expressly states that the purpose of the injunctive power is to avoid multiplicity of criminal proceedings.

Statutory analogies for an injunction sanction in a criminal statute are not lacking. The Sherman Law,[298] the Prohibition Law,[299] the National Industrial Recovery Act,[300] and the new Securities Act[301] as well as some of the state food and drug legislation[302] are all implemented with the injunction remedy. The provisions in these statutes are much broader and more direct than that contained in the bill. In an excess of caution, the draftsmen have limited the section to repetitious violations and have assimilated it to the public nuisance cases.[303] The legal necessity for the limitation is quite dubious, and it is highly questionable whether the constitutional difficulties are avoided by the qualifications. The obeisance to the assumed constitutional requirements may rob the remedy of effectiveness. One of the chief advantages of an injunction is its speed; to require proof of repetitious violations will often tend to defeat the purpose of the remedy. Moreover, it is not clear how many violations constitute a repetitious offense. Curiously, only the repetitious introduction of adulterated and misbranded articles may be restrained. As worded, it would seem that the government cannot proceed against the recipient, or in truth, anyone preparing or handling the illicit article save the shipper. Fortunately, the restraint upon false advertising is not so narrow. And the government is expressly spared the necessity of showing an intent to continue the statutory nuisance.

L. 580. For a federal statute providing for a maximum and minimum fine and imprisonment, see 14 STAT. 473 (1867), U. S. REV. STAT. §3242 (1878).

[296] See Sayre, *Public Welfare Offenses* (1933) 33 COL. L. REV. 55.

[297] *Id.* at 57 *et seq.*

[298] 26 STAT. 209 (1890), 15 U. S. C. A. §4. See also the Clayton Act, 38 STAT. 736, 15 U. S. C. A. §25; and the Wilson Tariff Act, 28 STAT. 570 (1894), 15 U. S. C. A. §§8, 9.

[299] 41 STAT. 314 (1919), 27 U. S. C. A. §34.

[300] PUBLIC No. 67, 73rd Cong. 1st sess. §3 (c) (1933).

[301] PUBLIC No. 22, 73rd Cong. 1st sess. §20, (1933).

[302] See N. J. COMP. STAT. (Supp. 1925) §81-156a (9); N. Y. LAWS 1909, c. 9, art. 2, §11.

[303] State v. Ryder, 126 Minn. 95, 147 N. W. 953 (1914); Popano Club v. State, 93 Fla. 415, 111 So. 801 (1927); Fulton v. State, 171 Ala. 572, 54 So. 688 (1911); see Carleton v. Rugg, 149 Mass. 550, 553, 22 N. E. 55, 56 (1889); *cf.* Board of Medical Examiners v. Blair, 57 Utah 516, 196 Pac. 221 (1921); (1933) 21 KY. L. J. 178; (1933) 27 ILL. L. REV. 560. The nuisance doctrine has been used frequently to sustain health regulations. See Brown, *Legislation for Health and Safety* (1929) 42 HARV. L. REV. 866, 873.

The constitutional objections to the use of the injunction remedy are that it endows equity courts with criminal jurisdiction and deprives the alleged violator of the right to a jury trial. But the familiar maxim that equity will not enjoin criminal acts refers to instances where private individuals seek to stir the conscience of the equity court; it does not relate to injunctions sought by the state nor to the direct enlargement of equity jurisdiction by legislation. As for the invasion of the right to a jury trial, the constitutional guarantee applies only to criminal proceedings[304] and a statute may therefore create a civil remedy of injunction which disregards the guarantee.[305] The equitable proceeding is none the less civil and to be governed by equity procedure merely because the act to be enjoined may constitute a crime or because the complainant is the Government.[306]

While the constitutional provision may thus be shown to be technically inapplicable, candor demands the admission that the governmental injunction affords an easy path for a subterranean encroachment upon the constitutional safeguard. The propriety of the use of the injunction in many instances is clear; in some cases the restraint will be oppressive. But to protect the stream of commerce against the introduction of illicit products or to protect it from obstructions and interference are well within the Congressional power.[307] Whatever authority there is amply sustains the inclusion of the injunction sanction.[308]

The present Act contains no provision for the use of publicity as a sanction save that after judgment of a court in a food or drug matter, notice of the judgment may be published in such manner as may be prescribed by the Departmental rules and regulations. In accord therewith, through July, 1933, 20,175 notices of judgments have been published. These notices are, however, legal summaries wholly inadequate to counteract the effects of false advertising and labeling. They go to a restricted audience and have proved ineffective. Without express statutory authority the Department has issued press releases. Possibly as a result of conservatism induced by the lack of such authority, these have been often too vague, general, and unpointed. The bill now places most extensive powers in the Secretary to publish the results of his findings and to disseminate such information regarding any food, drug, or cosmetic as he

[304] Article 3, §2, cl. 3 of the Federal Constitution provides: "The trial of all crimes, except in cases of impeachment, shall be by jury, and such trial shall be held in the state where the said crimes shall have been committed. . . ."

[305] U. S. v. Trans-Missouri Freight Ass'n, 166 U. S. 290, 17 Sup. Ct. 540 (1897); *In re* Debs, 158 U. S. 564, 15 Sup. Ct. 900 (1895).

[306] See cases cited *supra* note 305, and U. S. v. Lockhart, 33 F. (2d) 597 (D. Neb. 1929).

[307] U. S. v. Trans-Missouri Freight Ass'n, *supra* note 305.

[308] There is not much authority on the question. The distinctions are still tenuous and inchoate. The Supreme Court had little difficulty with the Sherman Law. See note 305, *supra*, and U. S. v. Elliott, 64 Fed. 27 (E. D. Mo. 1894); *cf.* U. S. v. Agler, 62 Fed. 824 (D. Ind. 1894); U. S. v. Railway Employees' Dept., 286 Fed. 228 (N. D. Ill. 1923). The federal courts have disagreed as to the validity of Section 23 of the National Prohibition Act. This section permits an injunction against bootlegging, no matter where carried on. See, upholding the provision, U. S. v. Lockhart, *supra* note 306; Simon v. U. S., 62 F. (2d) 13 (C. C. A. 9th, 1932); *cf.* U. S. v. Rosoff, 27 F. (2d) 719 (C. C. A. 2d, 1928). But *cf.* U. S. v. Cunningham, 21 F. (2d) 800 (D. Neb. 1927), app. dis., 24 F. (2d) 1021 (C. C. A. 8th, 1928), s. c. 37 F. (2d) 349 (D. Neb. 1929) (declaring the section unconstitutional).

deems necessary in the interest of public health and the protection of the consumer against fraud.[309] The publicity powers of the Secretary are thus placed upon a par with those possessed by many state food commissioners.[310] Certainly, if wielded properly and aided by an alert and fearless press, the weapon of publicity can become the most trenchant. It is difficult to envisage just what restrictions may encumber the issuance of publicity, yet one doubts if the privilege on the part of the Secretary will be considered absolute by the courts. It is interesting to note a holding that a federal court cannot entertain a petition for mandamus to restrain the issuance of a food inspection decision despite a showing that the unfavorable publicity would injure a patentee.[311]

In an effort to enlist the voluntary coöperation of the food, and drug industries the bill provides for a system of voluntary inspection.[312] The gist of the plan is as follows: any manufacturer or packer of any food, drug, or cosmetic sold in interstate commerce may apply to the Secretary for the service. The Secretary is given discretion to designate supervisory inspectors to examine and inspect all the premises, equipment, methods, materials, containers and labels used by the applicant. If the article is found to conform to the requirements of the law, it may be so marked and such other facts relating to its identity or quality may be similarly noted in accord with departmental regulations. The services are to be rendered only after the applicant pays fees in such amount as to cover costs of the inspection and the reasonable costs of administration. In view of this last provision for payment, the system is hardly open to the charge of expending public sums for private enterprise.[313] Yet the force of this sanction is not so innocently permissive and voluntary. By implication and the operation of the rule of *expressio unius est alterius exclusio* it denies to those who do not apply for the inspection the right to label and mark their products as products conforming to the federal law, a right now universally possessed by the packers and manufacturers subject only to the proviso that the claim be true. This denial raises a sharp question of discrimination and is not of too

[309] BILL, §21.

[310] *Cf.* CAL. GEN. LAWS (Deering, 1931) act. 57, §15; ILL. REV. STAT. (Cahill, 1929) c. 56b, §1; IOWA CODE (1931) §3050; N. D. COMP. LAWS ANN. (Supp. 1926) §2889a13; N. Y. CONS. LAWS (Cahill, 1930) c. 1, §22; MISS. ANN. CODE (Hemingway, 1930) §4974; TENN. ANN. CODE (Shannon, 1932) §6594; HAWAII REV. LAWS (1925) §1003; CAN. REV. STAT. (1927) c. 76, §22.

[311] U. S. *ex. rel.* Alsop Process Co. v. Wilson, 33 App. D. C. 472 (1909). The publicity provisions of the 1924 Revenue Act were held constitutional in Hubbard v. Mellon, 5 F. (2d) 764 (C. A. D. C. 1925), on the ground that such publicity is appropriate as a means of enforcing a legitimate power. A federal court does not have jurisdiction in an action to prevent a journalistic crusade by a state food commissioner as it is not an action against a state within the meaning of the Eleventh Amendment. Scully v. Bird, 209 U. S. 481, 28 Sup. Ct. 597 (1908). "If this publication is made to those dealing in the article, it would be within the duty of the commissioner in advising of contemplated prosecution. If such publications are libelous, the law affords other means of redress." Arbuckle v. Blackburn, 113 Fed. 616, 627 (C. C. A. 6th, 1902), app. dismissed, 191 U. S. 405, 24 S. Ct. 148 (1903). But state courts have enjoined publicity by food commissioners where the acts were deemed in excess of his authority. State *ex. rel.* Ladd v. District Court, 17 N. D. 285, 115 N. W. 675 (1908); Pratt Food Co. v. Bird, 148 Mich. 631, 112 N. W. 701 (1907).

[312] BILL, §22.

[313] See Note (1930) 18 CALIF. L. REV. 697.

sturdy validity. It should be noted also that the Secretary is under no duty to provide the service. Doubtless, his discretion must be exercised without arbitrary discrimination as between applicants, products, and classes of products.

Section 24 of the bill reads: "A right of action for damages shall accrue to any person for injury or death proximately caused by a violation of this Act." Section 24 is well-intentioned but may have most unexpected results. Does it add anything to the present state of the law? A violation today carries civil liability irrespective of privity in the case of misbranding and most types of adulteration.[314] The express provision for a civil right of action may help in the case of injuries occasioned by the consumption of "naturally" adulterated products.[315] Again, *prima facie* Section 24 gives a right of recovery where a consumer is injured by eating products shipped in interstate commerce by packers and manufacturers who fail to have licenses when required by the Secretary of Agriculture. Such a recovery for violation of license statutes has been denied on the ground that the violation does not proximately cause the injury.[316] The continuance of the condition of proximate causation might seem to negate a civil recovery for violation of the license provision; but the character of the license required under the bill coupled with the language of Section 24 may extend the cause of action.[317] The section does render obsolete any lingering question of privity of contract being needed for the recovery in tort.

But where the design of the legislative body has been to protect members of the public from particular types of injuries, the courts upon finding the design so limited have refused to permit the statutory violation to act as an avenue of recovery for the invasion of other interests.[318] If this be true where the limitations on the design have

[314] See notes 280, 281 *supra*, for the effect of violation of the Act. In many of the cases dealing with suits in negligence for food poisoning, the disregard of relevant state statutes does not speak too highly for the lawyer's art. The weight of authority as to the effect of the violation of a state food and drug law in a civil suit is that the violation constitutes negligence *per se*. Greenwood v. Thompson Co., 213 Ill. App. 371 (1919); Portage Markets Co. v. George, 111 Ohio 775, 146 N. E. 283 (1924); Fischer v. Golladay, 38 Mo. App. 531 (1889); Hendry v. Judge & Dolph Drug Co., 211 Mo. App. 166, 245 S. W. 358 (1922); Kelley v. Daily Co., 56 Mont. 63, 181 Pac. 326 (1919); *cf.* Sutton's Adm'r v. Wood. 120 Ky. 23, 85 S. W. 201 (1905). See Note (1933) 33 COL. L. REV. 868, 871 n. 16. But *cf.* Gearing v. Berkson, 223 Mass. 252, 111 N. E. 785 (1916); Culbertson v. Coca Cola Co., 157 S. C., 352, 154 S. E. 424 (1930); Tucker v. Graves, 17 Ala. App. 602, 88 So. 40 (1920); Travis v. Louisville & N. R. Co., 183 Ala. 415, 62 So. 851 (1913). The failure of the plaintiff to read or examine the label is not negligence as a matter of law. Hendry v. Judge & Dolph Drug Co., *supra*. But the violation must be the proximate cause of the injury. People's Service Drug Stores v. Somerville, 161 Md. 662, 158 Atl. 12 (1932). The negligent omission of the retailer to inspect the food is not such intervening cause as to give immunity to the manufacturer. Maddox Coffee Co. v. Collins, 167 S. E. 306, 185 S. E. 470 (1932). In accord with the law generally, the mere fact that the article conforms to government standards or has passed governmental inspection does not remove the question of negligence. O'Connor v. Armour Packing Co., 158 Fed. 241 (C. C. A. 5th, 1908); Kitterer v. Armour & Co., 247 Fed. 921 (C. C. A. 2d, 1917); Catani v. Swift & Co., 251 Pa. 52, 95 Atl. 931 (1915); Tiedje v. Haney, 184 Minn. 569, 239 N. W. 611 (1931). The allegation of a food and drug statute in a complaint may aid to convert a libel from one of goods to one of the person. *Cf.* Larsen v. Brooklyn Eagle, 165 App. Div. 4, 150 N. Y. Supp. 464 (2d Dept. 1914). But *cf.* Hopkins Chemical Co. v. Read Drug, etc. Co., 124 Md. 210, 92 Atl. 478 (1914).

[315] See note 281, *supra*. *Cf.* Mills Restaurant Co. v. Clark, 185 N. E. 470 (Oh. App. 1933).

[316] See Note (1932) 32 COL. L. REV. 712, 718.

[317] *Cf.* Goodwin v. Rowe, 67 Ore. 1, 135 Pac. 171 (1913).

[318] See Note, *supra* note 316, at 716.

not been expressed in the statute but have been judicially determined, *a fortiori* will it be true in an instance where the legislating body specifically adverts to the problem of civil recovery. When thus viewed, Section 24 is difficult to reconcile with the double aim of the statute: to guard the consumer from economic fraud as well as from bodily injury. Its effect would be to give violation of the Act non-conclusive force on the issue of negligence wherever the plaintiff seeks to recover for losses to his pocketbook. On the other hand, despite Section 24, the violation might still be deemed evidence of negligence in actions not covered by the expressly created statutory tort.[319] The omission of a cause of action for economic loss seems unfortunate. Even more unfortunate would be the case if courts were to take the position that Congress in enacting Section 24 and adverting to a recovery in tort had by its silence completely legalized contracts for the shipment and sale of products in violation of the new law.

The statutory defense of guaranty is continued with several changes[320] and extended to dealers who receive advertising copy but is expressly denied in all cases where the dealer's violation of the law is "wilful" and the dealer is prosecuted for such "wilful" offense.[321] The bill also exempts publishers, advertising agencies, and radio broadcast licenses for the wilful or non-wilful dissemination of a false advertisement if on request they furnish the name and post-office address of the person who contracted for or caused them to disseminate the false advertisement.[322]

LIMITATIONS OF THE BILL

The scope of the bill has been indicated. Some of its limitations have been considered but others remain for discussion or re-emphasis. As far as misbranding and adulteration are concerned transportation continues to receive the classic exclusive

[319] *Id.*

[320] BILL, §17 (e). Section 9 of the Act provided that the guaranty must be to the effect that the article is not misbranded or adulterated within the meaning of the Act. Section 17 (e) of the bill requires merely a guaranty that the person signing it assumes full responsibility for any violation. Under the Act, the guaranty may be given by the person from whom the dealer purchases the article; under the bill it must be given by the person from whom he receives the article or the advertising copy thereof.

[321] Section 17 (e) of the bill is specifically limited to prosecutions under Section 17 (b) and apparently is not available for prosecutions under Section 17 (c). Several of the states seem to have gone even further than the bill and have denied the defense of the guaranty where the dealer knew or ought to have known that the article was adulterated or misbranded within the meaning of the Act. Since "wilfulness" is often difficult to prove, the provisions of these statutes as to guaranty seem preferable to that of the bill. *Cf.* CAL. GEN. LAWS (Deering, 1931) act 57, §22; KAN. REV. STAT. ANN. (1923) §65-609; ILL. REV. STAT. (Cahill, 1929) c. §56b, §32. Section 27 (d) provides that no guaranty operates as a defense if the dealer continues to sell the article after notice by the state food commissioner that the article is adulterated or misbranded or if the dealer fails to preserve for the guarantor and deliver to him upon demand the sample left with the dealer by the commissioner. In Canada and England, the analogous defense of warranty has been severely restricted. See 18 & 19 GEO. V, c. 31, §29; CAN. REV. STAT. (1927) c. 76, §24; Freeman, *Labels as Warranties under the Adulteration Acts* (1928) 92 JUST. P. 808.

[322] BILL, §17 (d). The section as worded requires a prior request which is discretionary. The wording is poor, and the Department has already announced that it will be changed so that the publisher violates the law only if, after request, he refuses. The Federal Trade Commission joins the publisher in false advertising cases. *Cf. In re* McGavan, 11 F. T. C. 125 (1927). Indicating the liability under the federal statute of a publisher of an obscene advertisement, see U. S. v. Kelly, Fed. Cas. No. 15514 (D. Nev. 1876) 3 Sawy. 566.

emphasis. Misbranding and adulterating foods, drugs and cosmetics have not been made federal offenses and the result is not unlike waiting for an embezzeler to cross a state line before subjecting him to an arrest. The failure so to extend the law[323] may work especial havoc to the bill's severe punishment of the wilful offender since the wilfulness must be shown in conjunction with the introduction into commerce of the misbranded or adulterated package, and the violator may often be the purchaser who transports the goods rather than the maleficent manufacturer. On the other hand, the interstate transportation of falsely advertised articles is not barred, and such articles may not be seized under the present provisions of the bill. Possibly the consumer will be protected from such articles in the case of most types of adulteration. However, where the danger lies in the use of the drugs as advertised, the bill's failure to arrest the passage of the articles to the consumer's medicine cabinet seems difficult of justification. The control of cosmetics is incomplete. As the bill is now phrased (unless in the rare instance where the cosmetic is also a "drug"), economic adulteration of cosmetics emerges scathless.[324] There are no standards for quality or definition of identity authorized for cosmetics.[325] Cosmetic containers may be deceptive as to shape or fill and one cosmetic may be offered under the name of another.[326] Likewise the control of devices is far from complete. Under the bill's wording all types of receptacles for foods escape regulation.[327]

What is more serious is that the bill's excellent step in requiring affirmative preventive disclosure on the label is not paralleled by any like requirement as to advertising.[328] Too often the hurried consumer under the impetus of advertising buys first and reads the latter later if at all. False advertising may continue to include false statements regarding a competitor's products.

The new sanctions could be stronger. No encouragement is given to coöperative enforcement on the part of private individuals or consumers' groups.[329] In addition to the restriction on the injunction weapon which has been noted, there is no authority given to include in an injunction decree the requirement that the goods, labels and advertisements of violators be inspected and certified by the department for a suitable period of time at the expense of the violator. A provision for costs in criminal prosecutions would tend to make the administration of the new law self-

[323] That such a provision would be constitutional is hardly open to doubt in view of U. S. v. Ferger, 250 U. S. 199, 39 Sup. Ct. 445 (1919), upholding a statute making it a crime to forge a bill of lading used in interstate commerce.

[324] *Cf.* BILL, §5.

[325] Section 11 of the bill is confined to standards for foods.

[326] *Cf.* BILL, §2 (b), §2 (c).

[327] But these are subjected to an indirect control by §3 (a) (4), §3 (a) (6) of the bill. The regulation of containers of foods is a reasonable exercise of the police power. People v. Frudenberg, 209 N. Y. 218, 103 N. E. 166 (1913) (milk container).

[328] The only affirmative disclosure provision for advertising seems to be that if it includes the name of a disease for which a drug is not a specific cure but a palliative it must state that the drug is not a cure for such disease. *Cf.* BILL, §9 (b).

[329] *Cf.* N. D. COMP. LAWS ANN. (Supp. 1925) §2889a6; VT. GEN. LAWS (1917) §6276.

liquidating and if made mandatory, would offset the suspending of sentences.[330] It would be particularly salutary if a violator of the false advertising provisions were forced as a penalty to publish at his own expense and in the same circulating media of his deception and with like blare the details of his conviction. Such a publicity weapon has been used abroad.[331] The bill also makes advances in aid of the Secretary's investigations[332] but the absence of statutory provisions as to what should constitute prima facie evidence of violations[333] is to be regretted. But even with its limitations, the bill, if enacted, would mark an epoch in the federal protection of the consumer.

[330] *Cf.* N. D. COMP. LAWS ANN. (Supp. 1925) §2889b23; OHIO GEN. CODE (Page, 1931) §12759; PA. STAT. (1920) §71; CAN. REV. STAT. (1927) c. 76, §34.

[331] *Cf.* German Food Law *(Lebensmittelgesetz)* (1917) §16; French Trade-Mark Law (1857) art. 13; German Trade-Mark Law, §16. See KALLET & SCHLINK, *op. cit. supra* note 71, at 260 *et seq.*

[332] BILL, §§14, 15. Several of the states penalize interference with the government inspection. See note 23, *supra.*

[333] Many of the state food and drug laws provide that the certificate of the state analyst shall be *prima facie* evidence of the facts therein stated. See, *e. g.*, CAL. GEN. LAWS (Deering, 1931) act 57, §14; FLA. GEN. LAWS (1927) §3208; *cf.* CAN. REV. STAT. (1927) c. 76, §13 (3); 18 & 19 GEO. V, c. 31, §28 (3). Some provide that possession of the adulterated article shall be *prima facie* evidence; others that the doing of the prohibited act raises a presumption of intent to violate. See, *e. g.*, CAL. GEN. LAWS (Deering, 1931) act 57, §8; ILL. REV. STAT. (Cahill, 1929) c. 56b, §4; MINN. STAT. (Mason, 1927) §3807.

WHAT THE FOOD MANUFACTURER THINKS OF S. 1944

LAURENCE V. BURTON*

If the food manufacturer could be sure that he could attain perfection in mind-reading and in forecasting the thoughts that might sometime arise in the bureaucratic mind, his opposition to this attempt at regulatory legislation might be lessened. As it is, however, he is taking no chances and is doing his utmost to defeat it.

Ever since March 4, a marked change has come over the administrative philosophy of the United States, as far as it can be determined by a study of current events and current as well as pending legislation. The proposed revision of the Food and Drug Act, Senate Bill 1944, has been born of the same philosophic concept that gave birth to the other New Deal legislation. Indeed, on November 7, 1933, Mr. W. R. M. Wharton, chief of the eastern food and drug inspection district of the Food and Drug Administration, gave a radio broadcast in which he specifically stated that S. 1944 was an integral part of the New Deal.

Like all the rest of the New Deal activities, this bill is based on an idealistic concept, a concept which merits the support of all right-thinking manufacturers as well as the consuming population. The concept, well stated in the title of the Bill, is "To prevent the manufacture, shipment, and sale of adulterated or misbranded foods, drugs and cosmetics, and to regulate traffic therein; to prevent the false advertisement of food, drugs and cosmetics. . . ."

Like most of the New Deal legislation, the philosophy underlying this concept seems to be that the American public is incapable of governing itself any more, that it needs to be saved from itself by the guidance of a group of youthful economists, amateurs in the field of statecraft, who as yet seem to have failed to recognize that most statutes inevitably entail an economic reaction, and that economic reactions are almost always followed by political reactions. Political reaction, as used here, refers to the reaction of a group of citizens toward the government, and is not used in the popular sense which regards politics as the art of winning elections.

It is unfortunate that this important piece of pending legislation lacks a true understanding of the reaction that must needs follow a crusade, however worthy

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may be its objective. There are no decent food manufacturers, of the scores which have been consulted, who take exception to the obvious intent of the bill. Many have exclaimed that it is high time something was done about some of the current unethical and absurd or highly objectionable practices that exist in the food, drug and cosmetic industries today.

In the field of food manufacture it is recognized that, of the evils at which this bill is directed, some are causes of the uneconomic conditions prevailing in the competition for a place on the American dinner-table.

The food manufacturers agree that the objective of S. 1944 is a worthy one (unfortunately I cannot speak for drug and cosmetic manufacturers, because of unfamiliarity with their field), and furthermore they agree that the bill will without question enable the Food and Drug Administration to accomplish exactly what it has set out to do.

Further examination of the bill shows them that it does not stop at the point of elimination of evil practices—far from it. The bill is so broadly drawn that any manufacturer can read into it a multitude of distinct perils for the very existence of his own business. He believes these perils are very real, despite the fact that this legislation is not directed at him at all, and despite all assurances from its authors or from the Food and Drug Administration that they have not the slightest intention of interfering with the conduct of his affairs as long as he pursues his current policies.

His fear is based on the fact that the interpretations of the powers granted to the Secretary of Agriculture are not restricted in any way. Too much of the bill is worded in such a way that the regulations thus created are not to be found in the bill but will be found later in the minds of the successive Secretaries of Agriculture and the successive enforcement officers to whom certain powers must be delegated.

Some of these fears would never have come to light had not one of the authors of the bill, the Assistant Secretary of Agriculture, Professor R. G. Tugwell, revealed so much of his economic philosophy in various publications and public utterances. The world knows that he has visited Russia and has found its institutions acceptable, that apparently he believes that packaging and advertising constitute economic waste that should be prevented.

One should not discuss here the merits of those beliefs which are imputed to him, but we must face the inescapable fact that this bill is the creation of the minds of a few men, of which his is the most influential. And we must further face the fact that this bill apparently creates sufficiently broad powers so that his economic philosophy may be imposed on the food industries whether it is necessary or not.

The inevitable result of this fear is a growing opposition on the part of those who might conceivably be benefitted by the elimination of some of the practices which this bill seeks to stop. No food manufacturer will accept this piece of legislation, no matter how little it will apparently affect him, without the most vigorous opposition

that he can put up. And the reasons for his opposition are manifold, but primarily they are based on the principle that the exact meaning of many important sections of the bill are largely a matter of official interpretation by individuals. The manufacturer is not losing sight of the expense of law suits. Regarding litigation in the light of the long-standing belief that "if you win you lose," in this day of need for rigid economy no manufacturer willingly incurs the cost, even of a trip to Washington, to attend a hearing let alone entering a court action, unless it is unavoidable.

The fault that is found with this bill is not in its intent, but in its drafting. Through failure of the drafters to foresee the succession of reactions that are inevitable, the feeling is growing that it is far better to discard the whole measure than to allow it to go on the statute books containing such phrases as "if by ambiguity or inference it creates a misleading impression." The bill itself, as well as the propaganda now being conducted by the government, is open to the charge of ambiguity and inference.

To confer such drastic and absolute powers, as are conveyed under the permit section, that the Secretary of Agriculture has the power of life or death over a business, where only he has the right to adjudge the situation, is repellent to every manufacturer. If the authors of that section contemplate only supervision of the traffic in shellfish and/or milk, or those foods which may be a potential health hazard by reason of their frequent consumption in uncooked condition, by all means let that legislation be specified in the bill. It is then possible to consider the merits of that proposed section of the bill without the hampering effect of fearful prejudices which are bound to arise out of its present all-inclusive breadth.

To many executives in industry there is little doubt that their own foresight has been developed through constant exercise and has been tested by trial and error to a far greater extent than that of the inexpert, though earnest, zealots. The defensive reactions of the executive mind are therefor immediately aroused by many features of the bill such as the definition that adulteration occurs "if any valuable constituent has been in whole or in part abstracted" from a food. Although any well-informed person realizes that such a definition is aimed at the prevention of deception or fraud, many a food manufacturer realizes at once that the intent to deceive or defraud need not be shown by the government in order to make a successful prosecution. And as a result the flour miller can see in this clause a possible mandate to mill only whole wheat flour in case a whole-wheat faddist should come into power in the enforcement of the bill.

The canner foresees very definite harassing problems arising out of the use of the word "classes" in Section 6 dealing with misbranding. With the recent experiences and difficulties under the McNary-Mapes Amendment to the existing law, they should not be stigmatized as reactionary if they balk at this provision, as well as the provision that quality grades must be declared correctly on the label.

Another place where all manufacturers balk is on Section 13 which permits

government inspectors to examine "methods and processes" as well as the rest of the premises of a plant. No doubt these words mean one thing to the drafters of the bill, but to the manufacturer this means something else—the disclosure of formulas and any technical secrets irrespective of their relation to the stated intent of the bill.

And when he is required constructively to publish his formula under the provisions of Section 7 (f) his exasperation is entirely justifiable. Indeed, there seems to be hidden in the whole bill a distinct hostility to specialty or proprietary foods. One can understand the good purposes of some provisions of the bill, but in Section 7 (f) there is not discernible at this time any real improvements to be attained in its application to food over the provisions of the present law.

Many costly practical difficulties will arise from Section 7 (f). The ratio of various ingredients of many manufactured foods will vary with their relative costs, all of which will necessitate a manufacturer to have on hand a great variety of labels differing only in the relative position of wording of ingredients, if he is to be able to comply with this provision. It will double and sometimes triple the size of label inventories in certain lines of manufacture, and when it is realized that label inventories commonly run as high as $50,000 to $100,000 in large plants, it is realized that here is an unnecessary waste that should be avoided.

A ridiculous situation also arises under Section 7 (f) when assorted packaged foods, e.g., assorted chocolate candies, are labeled in compliance with its requirements. The top of a one-pound box of assorted chocolates is usually not large enough to carry all of the data required. Even the problem of correct labeling of a single piece such as an "O HENRY" candy bar is so overwhelming that one wonders what has become of the common sense of the drafters of the bill. Did they fail to discuss the practicability of this clause with any manufacturer?

These drafters have erroneously reasoned from the experience of Bureau of Animal Industry inspection service, that the Bureau of Food and Drug inspection could set up a system of voluntary inspection that would be avidly embraced by all food manufacturers, forgetting that the Bureau of Animal Industry inspector is largely employed as a pathologist for the inspection of carcasses for diseased animals. His job is really an integral part of the well organized production line. He performs a service that is useful to the meat packer as well as a service that is very beneficial to the public. But where, pray, can we find a parallel place for his services in other lines of manufacture?

If the food manufacture is aware of the real implication of Section 24, "A right of action for damages shall accrue to any person for injury or death proximately caused by violation of this act," he will oppose it or the whole bill even to its ultimate destruction. The opposition here arises from the fact that it opens the door wide to the ambulance chaser, be he lawyer or physician. It can make any violation of the law, however trivial, the basis of an attempt to collect easy money through its failure to distinguish between offenses which are *malum prohibitum* and *malum per se*.

Opinions have already been expressed that this section could easily break a hapless food manufacturer through the cost of defending *fake* damage suits which might be based on convictions where the offense is only *malum prohibitum*. There is, of course, no likelihood of evasion of responsibility where the offense is characterizable as *malum per se*. It seems advisable, however, in the interest of sound progress that the inhibitory character of this section be recognized and modified.

Whether the food manufacturer will sign up for voluntary inspection in case the bill becomes law is impossible to determine at this time. It will be necessary for the manufacturer to first ascertain just how much responsibility the government will accept in his plant.

The strangest anomaly in the bill is the complete absence of any provision to correct a serious problem of twenty-seven years' standing. The Bureau of Food and Drug Inspection has never granted an approval for an acceptable label, but has always reserved the right to prosecute for misbranding the hapless individual who has failed to guess rightly what the bureau really requires. Such extreme conservatism has no place in a bill of so radical a character. And to a manufacturer of long experience this defect of omission is amusing, to state it mildly.

The provision to prevent false advertising, however good its intent, is so worded that no manufacturer will lend his support to the measure. When it is not denied that under the phraseology of their bill it will be possible to jail a man for a year for such an innocuous statement in an advertisement as "Let Santa Claus bring you Blank's Chocolates for Christmas," or to inflict a similar penalty on a maker of carbonated beverages because his advertising may suggest that Eskimos have something to do with his product, it is high time to call a halt. The zeal for reform has gone to absurd limits. And when one learns that the real intent of the perpetrators of such legislative nonsense was to rush this bill through Congress as emergency legislation, in the special session in 1933, it is understandable why the clauses pertaining to advertising were so clumsily drawn. It takes more time to draft legislation which will merit our moral approval than was evidently possible to devote to this bill in the great haste in the Spring of 1933. The too all-inclusive features of Sections 9 and 17, particularly the admittedly pernicious implication of Section 17 (d), deserve the severest censure. Professor Tugwell's reputed belief that advertising is economic waste is apparently hard at work in this connection.

No manufacturer of foods opposes regulation of advertising which has for its intent, the purpose of defrauding the public. If the government's exhibit, popularly known as the Chamber of Horrors, is an index of the advertising which it hopes to prevent, then why in the name of common sense does not this bill more accurately describe the offense?

As long as this bit of legislation is pending, all kinds of manufacturers of both good and bad character are united in opposition to it, and the good manufacturer will not relent until it is plainly discernible, by even a business man, that he cannot be penalized by a fanatical interpretation of this bill.

The opposition to this bill is not an effort to perpetuate a *status quo* of liberty to continue to do the harmful things that the bill seeks to avoid. Rather it is an effort to avoid the multiplicity of absurdities and injustices that the bill would create.

Within the space limitations of this article it is impossible to discuss or even enumerate all of the objectionable features of S. 1944. The best that can be said for it is that it is a very inexpert attempt to attain a worthy end. It should be withdrawn and redrafted with greater deliberation and with the advice of the several industries to come under its jurisdiction.

A CONSUMER LOOKS AT THE FOOD AND DRUGS BILL

ARTHUR KALLET*

It would be an easy and pleasant exercise to catalog the improvements over the present food and drug law in the proposed new bill; for example, the provision for legal food standards, for the supervision of cosmetics, and for the extension of regulation to advertising. But when we finish our list, we still find a bill which, under our politically dominated bureaucracies, actually invites vitiation by the pressure groups it is intended to control.

The entire history of regulation in this field has clearly demonstrated that honest, wholesome, and safe products cannot be expected from private profit-seeking enterprise. It should have been recognized, after a sad quarter century of attempted and ineffectual control, that the production of drugs and the processing of most foods is no proper field for business individualism. If our plutocratic government under democratic forms will not tolerate public ownership, consumers might at least reasonably expect systematic, continuous supervision of manufacture and distribution so thorough that the government itself would be able to assure them an adequately wholesome and safe food and drug supply.

This is impossible under the theory of control accepted by the framers of the bill: that the public welfare can be safeguarded by the discovery of illegal products and their removal from commerce instead of by the forestalling of their production in the first place.[1] In practice this theory supposes that the seizures of a few packages or bottles[2] will cause manufacturers to forego the large and easy profits in many illegal products. Inquiry should have been made of criminologists as to the degree of social protection which can be achieved by "punishment" equivalent to taking a few cartridges away from an habitual criminal while leaving him his gun and his liberty. Punishment under the proposed law would amount to exactly this. Our bureaucracies and legal system and the motivations behind both being what they are, judicial actions would in most cases—as at present—be directed against canned chicken and liver pills, not against packers and nostrum makers.

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[1] The latter is now done (in legal theory) with meat and alcohol.

[2] Fines would probably be as infrequent and prison sentences as rare under the new law as under the old.

Even in this day of fast changing economic concepts, the framers of the bill still feared to deprive any individual, however ignorant or otherwise unqualified for great responsibility, of the seemingly sacred right to manufacture vital drugs or complex, potentially contaminated food products. Any ex-racketeer, barred by law from becoming a beer-runner or bucket-shop proprietor, could, under the proposed bill, legally manufacture hospital ether, digitalis, or Colchicum, or an infant food, without any question as to his special qualification, social responsibility, or the availability of any kind of supervision.

To be sure, provision is made for putting an offending *class of manufacturers* under permit, but only when the injurious nature of the products concerned "cannot be adequately determined after such articles have entered interstate commerce."[3] Although this section appears to be an attempt to reach inside state lines without jeopardizing the constitutionality of the bill, one might almost suspect that the brilliant counsel of the united nostrum manufacturers had written it, so well does it assure immunity to offenders or probable offenders. Imagine a political appointee's daring to clamp the lid on all manufacturers of a class of products because conditions of manufacture in some of the plants seem likely to introduce hazards; to put Squibb or Parke-Davis under permit, for example, in order to control irresponsible producers of digitalis or cod liver oil! And what an undertaking to prove that the injurious nature of the products cannot be determined after they have entered interstate commerce! This section would be immeasurably strengthened by adding to it a requirement for the placing of any individual manufacturer under permit after a stipulated small number of offenses, whether or not the injurious nature of his products can be determined after their entry into commerce.

The bill, likewise, would have the courts enjoin commerce in an article involved in repetitious offenses;[4] but it would not prevent the offending manufacturer from making and distributing other articles. It must be remembered, in considering both these sections of the bill, that the fear of tampering with vested interests which burdened the framers of the bill would bear down a thousand times more heavily on political appointees and socially indifferent courts faced with the execution of their provisions, and would therefore effectively nullify their implied purpose except in rare and flagrant cases that had happened to achieve wide public notice. It requires only the most cursory examination of the acts of officials and courts in comparable cases under the present Food and Drugs Act to see that no other result would be possible.

An alternative regulation, based upon the seemingly proper assumption that there is no greater right to manufacture and sell foods and drugs than to brew beer or to denature alcohol, would require the licensing of every manufacturer of drugs and cosmetics, and every processor and canner of foods for interstate commerce. Exceptions would be granted only on affirmative proof, to be passed upon by a board of

[3] Food and Drugs Bill, 73rd Cong., 1st Sess., S. 1944, §12(a).
[4] *Id.* §19.

food or drug technologists (not political appointees) that a product or process involves no slightest hazard to consumers. Licenses would be granted only to individuals possessing the technical knowledge and experience necessary for producing specified products, or to corporations employing such persons in responsible managerial positions, where they would be made strictly accountable, at law, *as individuals*. Freedom of access by the proper officials to plants and to all records would be another requirement in the granting of licenses. Further, such essentials as minimum equipment, sanitation, tests, etc. could be covered.

Every distinct product intended for interstate commerce, as well as the producers thereof, would be subjected to license, thereby preventing from the start interstate trade in illicit foods and drugs and worthless medicines. The bonding of responsible individuals, provision for continuous inspection, and other devices could provide an indispensable degree of control over materials, processes, and products. Such devices would no more interfere with individual liberty than do our present automobile and driver licensing systems and traffic control measures. Furthermore, control could be taken, to a large extent, from technically unqualified judges and placed in the hands of process experts and laboratory workers, where it belongs. It is not believed that this line of control would bring our food and drug supply near perfection; it would, however, afford fair protection to consumers, although it might work hardships on more or less well-intentioned but incompetent entrepreneurs.

A part of the above proposal is embodied in the modification of the administration bill introduced by Congressman Sirovich. Dr. Sirovich would have every packaged drug bear a registered label[5]—a vast improvement over the general labeling provisions of the administration bill, but still seriously defective in that it would place the approval of labels in the patent office where this function cannot be competently exercised, and decidedly does not belong.

There is probably no more serious defect in the bill than the broad discretionary powers vested in the Secretary of Agriculture. The phrasing of the bill would permit the Secretary to abstain completely from taking regulatory actions along many lines, and no consumers' proceeding in any court could compel him to do more than use his own judgment. The bill, as written, permits him to choose at many important points between the safeguarding of the public and the shielding of food and drug manufacturers. By placing in the hands of the Secretary for final determination the establishment of standards, and such highly technical questions as degree of toxicity, tolerances, and other crucial points of control—casually treated in the bill—the way is opened for a process of attrition by which the industries can break down whatever effectiveness the law may have in the beginning.

There is food for sad reflection in the frenzied energy with which the nostrum manufacturers are already preparing to defeat the bill. Every advertisement sent to newspapers and magazines by many medicine makers is accompanied by the sug-

[5] 73rd. Cong., 1st Sess., H. 6110 (1933).

gestion that the publication protest the new bill if it wishes to receive more such profitable advertisements. This line of attack is, of course, obvious; but the industry plans to go even to the length of organizing the truckmen who transport the nostrums, the owners of their factories, and everyone else on whom they can lay their hands through related economic interests, to defeat the bill.

Whether or not the pressure they bring to bear succeeds, we are concerned here with the knowledge that, should the bill pass, the same intense pressure will unremittingly be brought to bear on the Secretary of Agriculture for years to come. And in the end, perhaps after three or four administrations have come and gone, the Secretary's power to exempt the industries from many of the regulatory provisions which they most fear would inevitably result in the emasculation of control.

The bill, as written, would rightfully put an end to the wide sale of such nearly worthless preparations as Mercurochrome (in aqueous solution), Listerine, and Lydia Pinkham's Vegetable Compound. It requires little imagination to visualize the nature of the industry's offensive against such an un-American, communistic, anti-Recovery program—the wilful destruction of honest, ethical (and profitable) business; and only slight prophetic gifts to realize that the offensive would succeed.

There is not the remotest possibility that any politically appointed Secretary of Agriculture could long withstand the constant organized clamor from the food and drug industries and their friends in and out of Congress for the lowering of standards, the stealthy increasing of tolerances on toxic substances and adulterants, and the general relaxation of enforcement which the bill, in a dozen different ways, virtually invites. The bill makes possible a repetition of the long series of acts by which the present law was emasculated; for example, the adoption by the Secretary of Agriculture under pressure from the Maine fish packers, of a definition for sardines formulated in a business-fostering bureau of the Department of Commerce instead of in the proper technical bureau of the Department of Agriculture. This decision, made within three months of the effective date of the Food and Drugs Act (January 1, 1907), included in the definition of "sardines" all varieties of small fish similar to genuine sardines. Other decisions, like this one clearly contrary to the intent of the law, permitted the renaming of glucose and cornstarch syrup as "corn sugar" and "corn syrup"; the importation of canned vegetables made artificially green with salts of copper; and the use of benzoate of soda and benzoic acid as preservatives.

While it will of course be said that such yielding to pressure is unlikely under the present Secretary of Agriculture, he recently made a decision far more dangerous to the public welfare than those cited above—which only shows the futility of trusting, in a profit-motivated society, to the resistance to pressure of any public official, however well-intentioned he may be personally.

This decision involved the amount of lead remaining on apples which had been sprayed with lead arsenate insecticide. Ignoring a previous decision (unenforced) by the Chief of the Food and Drug Administration that no lead residue would be

permitted because of the great hazard from this cumulative poison, the Secretary legalized a residue of fourteen thousandths of a grain of lead per pound of fruit, an amount sufficient to endanger the public health and to contribute to chronic, insidious lead poisoning in many susceptible individuals. This, despite the fact that the residue can be inexpensively removed, either by the growers or by the government. Not even this ruling satisfied the fruit growers, however, and, led by Senator Byrd of Virginia (who is the largest of American applegrowers) and Governor Moore of New Jersey, they exerted sufficient pressure in the proper high places to cause an increase of nearly fifty per cent in the permissible residue.

Nearly all decisions of this kind are technical in nature, not administrative, and should be made by technologists, insulated from outside pressures and influences, and with tenure independent of political control. Whether any lead should be permitted to remain on fruits and vegetables, and if so, how much can be safely tolerated, should be decided by toxicologists, not by a member of the Cabinet or an undersecretary with political or general administrative duties.

A new food and drug bill could provide for nothing more important than the establishment of independent boards of toxicologists without whose unanimous approval no tolerance would be permitted for any poison or suspected poison; whose unanimous approval would also be required for any increase in an official tolerance. The bill leaves the entire question of the determination of what is or may be injurious to health to the judgment of the Secretary who may or may not, at his own discretion, seek competent advice; or, having sought it, may follow or disregard it as he wills. The bill requires no research in the control of food and drug processing or in toxicology; and in no way would it prevent the suppression of commercially undesirable technical findings on poison hazards, the very type of suppression that has been practiced under the present law since the days of Harvey Wiley. Whatever the present Secretary of Agriculture may or may not do with the freedom allowed him in these matters, it is foolhardy to suppose that future secretaries will follow policies based upon consideration for the public good.

Wide, unremitting publicity exposing every violation and every violator of the law is absolutely essential for the protection of consumers. Not only does such publicity provide the public with a defense against the purveyors of illegal products, but it also builds up the public counter-pressure for strict enforcement necessary to combat governmental laxity under business pressure. The likelihood that any considerable volume of effective publicity would result from the publicity section of the bill as now written is extremely slight. The bill provides that "The Secretary shall cause to be disseminated such information regarding any food, drug, or cosmetic as he deems necessary in the interests of public health and for the protection of the consumer against fraud."[6] If the purpose of this section is to be accomplished, the law must make mandatory searching publicity for every phase of every violation from

[6] Food and Drugs Bill, *supra* note 3, §21.

the laboratory findings to the ultimate disposition of the case. The flow of facts concerning violations must not be a matter of official discretion; for if it is, it can safely be predicted that there will be no publicity except, as now, when very small merchants or producers, in most cases foreigners, are involved. The publicity section of the bill is apparently an attempt to perpetuate the theory of present enforcement officials that it is better to jeopardize the welfare of all consumers than to risk publicity unfavorable to a single large-scale producer who might prove to be quite innocent.

The section of the bill relating to advertising, good as it is in intent, presents an enforcement problem which could not be handled with a staff devoted entirely to this phase of control even if such a staff were several times as large as that which the entire enforcement division is likely to have. Imagine the effort required to police advertising for food, drugs, and cosmetics in newspapers, magazines, radio, billboards, handbills, counter displays, and whatever other media hardpressed and ingenious advertisers can invent, to discover if the advertising "is untrue, or by ambiguity or inference creates a misleading impression. . . ."[7] Here at last are jobs aplenty for all of the literate unemployed. In appraising the possible effectiveness of such control, it must be borne in mind that not one out of perhaps a thousand advertisements in the field of drugs and cosmetics intended for general consumption is free from untruth, or from ambiguity or inference intended to create a misleading impression.

The difficulty of advertising control would be about halved, though still tremendous, if the framers of the bill had not been frightened by the awful cry of censorship from requiring advance submittal of copy. Newspapers and magazines constantly boast that they censor their advertising. But the suggestion that such censorship be placed in the hands of anyone of actual competence who is not overly concerned about advertising revenues, throws the publishers into a passion over the "freedom of the press." They might better be concerned with the pernicious influence of the advertisers over their news and editorial columns, as evidenced by the flood of apparently inspired editorials condemning the proposed bill.

The control of advertising might be further simplified by requiring the registry of claims to be made for advertised food, drugs, and cosmetics (the American Medical Association does this for food products submitted for its acceptance) and permitting only approved claims to be made. Or, if this would cause too many suicides in the advertising agencies, the advertisers might be permitted to write, recite, or picture what they will, provided every advertisement making any claims whatsoever, also carries the officially accepted and registered claims.

The bill's requirement that formulae be stated on drug labels should be extended to advertising. The framers of the bill would have advertising controlled only because they know that people buy on the strength of the advertising they see or hear,

[7] *Id.* §9 (a).

not because of statements on labels. This reasoning should apply to formulae as well as to claims. Here we might follow the good example of the Philippines, where the publication of formulae in drug advertisements is now required by law.[8]

Certainly it is to be hoped that any advertising control finally enacted will not, as is now proposed, exempt advertisements in medical, pharmacological, and scientific publications. Curious as it may seem to some, these publications are also concerned about advertising revenues, and regularly carry their share of ballyhoo for worthless and sometimes dangerous preparations. And, alas, the doctors and druggists are taken in by the advertisers almost as easily as the uninformed layman. A notorious example is the advertising for Mercurochrome which has appeared regularly in the publications of the American Medical Association, despite the fact that the unreliability of this antiseptic in the usual solution has been exposed by a dozen authorities, including the Association's own committee on the subject. Unfortunately, some thousands of physicians who read interestingly worded advertisements but not dry-as-dust reports on antiseptics, continue to recommend Mercurochrome to their patients.

Possibly with the hope of using to advantage the torrent of the anti-prohibition sentiment, the medicine makers are losing no opportunity to declare that the proposed bill would deprive ailing citizens of the sacred right of self-medication. This, of course, is nonsense; but the problem of self-medication deserves careful consideration, nevertheless, in the regulation of proprietary medicines. At least until we have socialized medicine, many millions of persons will of necessity continue to diagnose their own minor ailments and to select their medicines. If a new law drives the dangerous and completely worthless nostrums off the market, it will be doing a valuable service for these people. A further and more valuable service could be done by making provision for the certification of a small list of open formula medicines,[9] safe and reasonably efficacious for self-medication, to be manufactured by qualifying producers under license. Standard precautionary labels and advertisements would, of course, be stipulated.

The framers of the bill apparently assumed that the control of food and drugs should remain in the Department of Agriculture. The danger to consumers in having a control activity at times strongly antagonistic to the interests of food and drug producers in a Federal department intended to promote the distribution and consumption of such products, is evident from the aforementioned decision on lead residue. The only logical place in the existing government services for food and drug control is the Public Health Service. Unfortunately, however, the Public Health Service is part of the Treasury Department, where, it must be admitted, its scientific integrity has suffered grave indignities. If this bureau can be given autonomy and a chance to go straight, food and drug control should by all means be transferred to it.

In any event, there is probably strong justification for such a transfer. Since the Service is under the immediate direction of physicians, it might be possible to have

[8] 2 PHILIPPINE PENAL CODE (1930), Act No. 2342, §3.
[9] The formulae would require periodic review by the certifying body.

foods and drugs controlled by men with a clearer conception of the nature of hazards involved and less concern for business necessities. This transfer has been discussed from time to time during the past several years. The determined and invariable opposition of the food and drug journals is, perhaps, a strong point in its favor. There is, for example, reason for grave suspicion of the manner in which the public is now being protected, when we read such items as the following from the *Oil, Paint and Drug Reporter:*

> Out of long experience, the Department of Agriculture has got a reasonable conception of the economic importance of the act. It has come to a fair measure of recognition of the industrial problems involved in compliance with the law. It is not inconsiderate of the right of manufacturers to be heard and to be informed. Although a more satisfactory administration of the act in certain particulars is possible, the situation could be worse; and it would be worse if the act were administered by the Public Health Service.

In addition to the transfer of control, it would be desirable to define, in the bill, the qualifications of the heads of the control divisions in order to insure technical rather than political competence. It cannot be too strongly emphasized that to be effective, control must be taken out of politics. This ideal can be approached only by precise legislative definition of the qualifications of officials; by the setting up—again by legislation subject to amendment only by Congress itself and not by discretionary appointment—of independent boards of technologists for the establishment of standards, and the determination of questions of toxicity, tolerances, etc., the decisions of which will be subject to no administrative review.

It is recognized that the proposals briefly sketched in this article would do violence to those "rights" which are considered inalienable by all sound business men. And if our legislators find, after due deliberation, that the food and drug business men must be protected, the consumer can only walk warily until another "new deal" throws private enterprise out of such vital industries altogether.